



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA-2021-N-0555]

RIN 0910-AI21

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is proposing to establish a regulatory category for over-the-counter (OTC) hearing aids and to make related amendments to update the regulatory framework for hearing aids. Specifically, we propose to define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with a new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that would become obsolete as a result of changes to the hearing aid requirements. This action, if finalized, would more clearly define prescription hearing aids; however, it would not change the classification of existing device types. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit written comments (including recommendations) on the collection of information under the Paperwork

Reduction Act of 1995 by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2021-N-0555 for “Establishing Over-the-Counter Hearing Aids.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18,

2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) to the Office of Management and Budget (OMB) at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review – Open for Public Comments” or by using the search function. The title of this proposed collection is “Medical Device Labeling Regulations.”

FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301-796-5620, Srinivas.Nandkumar@fda.hhs.gov.

With regard to the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

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Executive Summary

Purpose of the Proposed Rule

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention. Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price). FDA is proposing rules to address some of these concerns.

Moreover, the FDA Reauthorization Act of 2017 (FDARA) directs FDA to establish a category of OTC hearing aids through rulemaking, and FDARA sets forth various requirements for OTC hearing aids, including preemption provisions. In addition to protecting and promoting the public health, we have developed these proposed rules to establish the OTC category and implement the requirements of FDARA.

Summary of the Major Provisions of the Proposed Rule

FDA is proposing to establish a regulatory category for OTC hearing aids to improve access to hearing aid technology for Americans. OTC hearing aids will be intended to address perceived mild to moderate hearing loss in people age 18 or older. Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category. We believe the proposals set forth in this rulemaking will protect the public health by providing reasonable assurance of safety and

effectiveness for hearing aids, as well as promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology.

Among other things, FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining OTC hearing aids and providing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls. We are proposing general controls for OTC hearing aids consistent with FDARA. Moreover, because the FD&C Act specifies that OTC hearing aids are those that use the same fundamental scientific technology as air-conduction hearing aids, we would realign the existing classification regulations for hearing aids by sound conduction technology. However, the realignment would not affect the device class or premarket notification exemption status of any existing device. On the effective date of the final rule, we would realign current product codes to correspond with the revised regulations for consistency but would not otherwise change the codes.

This rulemaking also affects other existing regulations that apply to hearing aids. FDA has established device restrictions for hearing aids that include labeling requirements as well as conditions for sale. We are proposing to remove these device restrictions for hearing aids, and establish a new regulation for prescription hearing aid labeling. Further, FDA has by regulation granted or denied exemptions from Federal preemption for State requirements pertaining to hearing aids. The removal of the device restrictions on hearing aids, as well as certain provisions of FDARA, impact most of these previous exemption decisions, for example, by altering their scope. We are proposing to remove the regulations codifying these decisions and establish other regulations clarifying some of the effects of statutory preemption under FDARA.

Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices intended for human use. Hearing aids are devices intended for human use and so are subject to, among other requirements, the device provisions of the FD&C Act. FDA has authority to establish regulatory controls needed to provide reasonable assurance of safety and effectiveness

for these devices. As such, FDA is establishing regulatory controls for OTC hearing aids and amending regulatory controls for prescription hearing aids.

Specific to OTC hearing aids, the FD&C Act and FDARA authorize multiple controls, including authority for FDA to establish requirements for device labeling, output limits, conditions for sale and distribution, and other requirements that provide reasonable assurance of safety and effectiveness of OTC hearing aids. FDARA specifically directs FDA to establish a category of OTC hearing aids by regulation that must include the aforementioned requirements.

More generally, the FD&C Act further provides for labeling requirements as general controls such that devices (and other medical products) will not be misbranded. The FD&C Act also authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. We are proposing the following regulations pursuant to these authorities and to fulfill the directive under FDARA.

Additionally, both the FD&C Act and FDARA include preemption provisions applicable to hearing aids.

Costs and Benefits

This proposed rule to establish OTC hearing aids and align other regulations, if finalized, would generate potential cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. The proposed rule, if finalized, would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. We estimate benefits of between \$6 million and \$147 million per year based on 5th and 95th percentile Monte Carlo results with a mean of \$63 million per year. We estimate annualized costs of between \$1 million and \$2 million per year based on 5th and 95th percentile Monte Carlo results with a mean of \$1 million per year.

Combining benefits and costs, we used Monte Carlo analysis to estimate annualized net benefits of between \$5 million and \$145 million per year based on the 5th and 95th Monte Carlo percentile results with a mean of \$62 million per year at both 3 percent and 7 percent discount rates.

Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/Acronym	What It Means
510(k)	A premarket notification for certain devices
ANSI	American National Standards Institute
ASA	Acoustical Society of America
CFR	Code of Federal Regulations
CTA	Consumer Technology Association
dB	Decibel
dBA	A-weighted decibel
EA	Environmental assessment
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDARA	FDA Reauthorization Act of 2017
FONSI	Finding of no significant impact
FR	Federal Register
GMPs	Good manufacturing practices
Hz	Hertz
ISO	International Organization for Standardization
MSW	Municipal solid waste
NASEM	National Academies of Sciences, Engineering, and Medicine
NIOSH	National Institute for Occupational Safety and Health
OMB	Office of Management and Budget
OSPL90	Output sound pressure level with 90-dB input
OTC	Over-the-counter
PCAST	President's Council of Advisors on Science and Technology
PRIA	Preliminary Regulatory Impact Analysis
PSAP	Personal sound amplification product
Pub. L.	Public Law
QS	Quality System
SPL	Sound pressure level
U.S.C.	United States Code

I. Background

FDA is proposing to define and establish general controls for an OTC category of hearing aids. We intend these proposals to provide for reasonable assurance of safety and effectiveness for these devices and improve access to and foster innovation in hearing aid technology for Americans, thereby promoting and protecting the public health. We would make various other

revisions, as described in this document, to align existing regulations with statutory requirements and the new OTC category.

A. Need for the Regulation

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life (Refs. 1 and 2). Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention (Ref. 3). The use of hearing aids has been linked to, among other health benefits, reductions in the incidence or severity of cognitive decline, depression, and other health problems in older adults (Ref. 3a and 3b). Additionally, benefits of hearing aid use can include improved social participation and a better quality of life.

Besides health benefits for individuals, more-widespread adoption of hearing aids could have broader effects. By increasing social participation, hearing aids could help to improve inclusion of individuals in family, economic, civic, and religious life. Thus, reducing barriers to hearing aid access might contribute to such improvements. This could be particularly true for people of color, rural Americans, low-income individuals, and others for whom barriers to hearing aid access may be especially burdensome.

Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price) (Ref. 4). In addition, stakeholders have cited Federal regulations that require specific labeling and conditions for sale, initially implemented in the late 1970s, as barriers to access (e.g., Refs. 5 to 7). This document proposes a number of changes to the regulatory framework for hearing aids to remove or reduce barriers to certain air-conduction hearing aids for perceived mild to moderate hearing impairment-- a type of impairment often associated with aging--that have the potential to be of great benefit to the public health.

These proposals follow the enactment of FDARA, which included provisions directing FDA to establish regulatory requirements for a new category of OTC hearing aids and amended the FD&C Act to add section 520(q) (21 U.S.C. 360j(q); see Pub. L. 115-52). Section 520(q)(1) of the FD&C Act defines OTC hearing aids, in part, as devices available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. Section 520(q)(2) of the FD&C Act requires that such devices be subject to the regulations FDA issues for them in accordance with section 709(b) of FDARA.

Section 709(b) of FDARA requires that FDA establish a category of OTC hearing aids that includes, among other elements, requirements to provide reasonable assurances of the safety and effectiveness of these devices. We also make multiple proposals to prevent the sale of OTC hearing aids to or for people younger than age 18. This document does not, however, propose to create or classify a new device type.¹ Further, this document does not propose to exempt additional devices from the premarket notification requirements under section 510(k) of the FD&C Act, commonly referred to as “a 510(k)” (21 U.S.C. 360(k)). Section IV of this document discusses our findings regarding premarket notification in more detail.

We are simultaneously proposing related changes to the regulatory framework that currently applies to all hearing aids, as they are defined in § 801.420 (21 CFR 801.420), in light of the new OTC category and to ensure consistency across rules pertaining to hearing aids (see § 801.420(a)(1)). Detailed information about each proposal appears in section III.

B. Current Regulatory Framework for Hearing Aids

¹ “Device type” as used in this document has the same meaning as “generic type of device” in 21 CFR 860.3(i) (a “generic type of device” means “a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness”).

Hearing aids, as defined in § 801.420(a)(1), are currently restricted class I and class II devices of multiple types. A summary of the current regulatory framework for these devices appears in table 1.

Table 1.--Summary of Current Regulatory Framework

Classification regulation, 21 CFR Section	874.3300	874.3305	874.3315	874.3325	874.3950
Device Restrictions	Restricted	Restricted	Restricted	Restricted	Restricted
Class I, 510(k) exempt ¹	Air-conduction (“legacy”)				
Class II, 510(k) exempt ¹		Wireless air-conduction			
Class II	Bone-conduction		Tympanic membrane contact hearing aid	Self-fitting air-conduction	Transcutaneous air-conduction hearing aid system
Product codes	ESD, LXB, MAH, LRB, LDG	OSM	PLK	QDD	NIX

¹ 510(k) exemptions are subject to the limitations in 21 CFR 874.9.

1. Hearing Aid Classifications

Hearing aids are class I and class II wearable sound-amplifying devices intended to compensate for impaired hearing. They currently fall under five classification regulations (the following references are to sections in Title 21 of the CFR):

a. Hearing aid (§ 874.3300 (21 CFR 874.3300)). This device type includes air-conduction (class I, 510(k) exempt, subject to the limitations of exemption in § 874.9) and bone-conduction (class II) hearing aids. Class II bone-conduction hearing aids require a 510(k) notification. These are all restricted devices.

b. Wireless air-conduction hearing aid (§ 874.3305 (21 CFR 874.3305)). This device type is a hearing aid that incorporates wireless technology in its programming or use, for example, controls over Bluetooth. These devices are class II restricted, subject to the special controls that have been issued for these devices, and 510(k) exempt, subject to the limitations of exemption in § 874.9.

c. Tympanic membrane contact hearing aid (§ 874.3315 (21 CFR 874.3315)). This device type is a prescription device that compensates for impaired hearing. Amplified sound is

transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

d. Self-fitting air-conduction hearing aids (§ 874.3325 (21 CFR 874.3325)). This device type is a hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

e. Transcutaneous air conduction hearing aid system (§ 874.3950 (21 CFR 874.3950)). This device type consists of an air-conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal. These devices are class II restricted, subject to the special controls that have been issued for these devices, and require a 510(k) notification.

Devices of these types may be either prescription (for example, devices for insertion deep in the ear canal) or non-prescription devices (which include the majority of air-conduction hearing aids).² For the purposes of this rulemaking, we refer to non-wireless, non-self-fitting, air-conduction hearing aids as “legacy hearing aids,” which means all air-conduction hearing aids currently within § 874.3300 but not air-conduction hearing aids currently within §§ 874.3305, 874.3325, or 874.3950.

2. Hearing Aid Restrictions

Hearing aids are currently subject to a set of restrictions on sale, distribution, and use, established in accordance with section 520(e) of the FD&C Act. We will refer to those as

² We use the term “non-prescription” because the FD&C Act, as amended by FDARA, defines OTC hearing aids and requires FDA to undertake rulemaking to establish the OTC category. As such, no hearing aid is yet OTC within the meaning of section 520(q) of the FD&C Act. We use “non-prescription” to avoid confusing the intended uses of current devices with devices that would eventually meet the OTC Hearing Aid Controls.

“Hearing Aid Restrictions,” and they include requirements for professional and patient labeling, as a well as conditions for sale (see §§ 801.420 and 801.421 (21 CFR 801.420 and 801.421, respectively)). All legacy hearing aids, wireless air-conduction hearing aids, and self-fitting hearing aids (as well as other device types) fall within a separate, broader definition of hearing aids in § 801.420(a)(1), and therefore are currently subject to these restrictions.

Among other requirements, § 801.420 specifies that the User Instructional Brochure labeling for hearing aids contain a warning statement for hearing aid dispensers that prompts them to advise prospective purchasers to consult with a physician if any of the listed medical conditions are present (see § 801.420(c)(2)). We will refer to these medical conditions as “red flag” conditions in this proposal. The rule further prescribes a notice to prospective users and an additional statement about hearing loss in children (see § 801.420(c)(3)). It also requires the disclosure of technical data useful in selecting, fitting, and checking the performance of hearing aids (see § 801.420(c)(4)).

Currently, § 801.421 specifies a number of conditions for sale for hearing aids. Such conditions include that a prospective user must present to the dispenser a signed statement of medical evaluation from a physician prior to sale (see § 801.421(a)(1)). However, a prospective user who is 18 years of age or older may waive the medical evaluation requirement by signing a statement with a prescribed advisement (see § 801.421(a)(2)). A dispenser must provide an opportunity for the prospective user to review the User Instructional Brochure prior to signing a waiver and the sale of a hearing aid (see § 801.421(b)). Manufacturers and distributors must provide sufficient copies of User Instructional Brochures to dispensers, and upon written request, to prospective users; dispensers must similarly provide the brochures (or the name and address of a manufacturer or distributor to obtain a brochure) to prospective users upon request (see § 801.421(c)). Dispensers generally must retain a copy of a medical evaluation statement or signed waiver for 3 years (see § 801.421(d)).

However, we announced in a guidance entitled “Conditions for Sale for Air-Conduction Hearing Aids” that we do not intend to enforce the medical evaluation, waiver, or recordkeeping requirements of § 801.421 with respect to prospective purchasers who are 18 or older (Ref. 8).

In addition to other applicable misbranding and adulteration provisions in sections 501 and 502 of the FD&C Act (21 U.S.C. 351 and 21 U.S.C. 352, respectively), hearing aids are currently subject to misbranding provisions for restricted devices under section 502(q) and (r) of the FD&C Act. Section 704(a) of the FD&C Act (21 U.S.C. 374(a)) authorizes FDA to inspect, among other things, certain records relating to restricted devices.

3. State Requirements for Hearing Aids

Under certain circumstances, State requirements apply to hearing aids notwithstanding Federal requirements. In general, FDA’s regulation of hearing aids preempts State law, meaning that a State or a political subdivision (e.g., a city) may not establish or continue in effect its own requirement if that requirement is “different from, or in addition to,” a requirement under the FD&C Act (see section 521(a) (21 U.S.C. 360k(a))). Many States have established requirements equivalent to § 801.420 or § 801.421 (i.e., not “different from, or in addition to” those regulations), which are not preempted by these Federal requirements.

However, for other State requirements, FDA has granted and denied exemptions from preemption under section 521(b) of the FD&C Act for some States that have applied. FDA responds to applications for such exemptions by regulation, codified in subpart C of part 808 (21 CFR part 808). Most of these regulations relate to hearing aids, and in some of these regulations, FDA has granted exemptions--meaning those States’ requirements apply instead of, or in addition to, FDA’s requirements--for:

- Specifying the physician expertise needed to examine prospective purchasers who are younger than 18 years of age;
- Advising purchasers when to seek medical attention based on “red flag” conditions;

- Providing purchasers with certain information and disclosures on receipts and other documentation;
- Recordkeeping requirements in addition to the Hearing Aid Restrictions; and
- Providing written notice of a money-back guarantee where a State court held the State requirement was preempted.

And FDA has denied exemptions--meaning the States could not establish or continue in effect requirements--for:

- Removing the waiver option for prospective purchasers who are 18 years of age or older;
- Lowering the age at which a waiver of medical examination prior to purchase was available;
- Changing the expertise for examinations, when conducted, for people 18 years of age and older;
- Prohibiting certain marketing claims about improving hearing; and
- Adopting different device testing standards.

FDARA added a separate Federal preemption provision for State and local laws, regulations, orders, or other requirements (for brevity, we will refer to “State or local requirements” in this rulemaking) specifically related to hearing products (FDARA section 709(b)(4)).³ That provision may affect the applicability of State or local requirements for OTC hearing aids. Section III.G discusses the OTC hearing aid preemption provisions and the effects of this rulemaking.

4. Hearing Products not Regulated as Hearing Aids

FDA does not consider personal sound amplification products (PSAPs) to be “devices” within the meaning of section 201(h) of the FD&C Act (21 U.S.C. 321(h)) when they are not intended to aid a person with, or compensate for, impaired hearing and do not otherwise meet the

³ Additionally, FDARA section 709(b)(5) addresses the effect of section 709 on certain private remedies.

device definition. Such PSAPs are not subject to medical device regulations, nor would the proposed requirements of this rulemaking apply to such PSAPs.⁴ Note that the name of a product on its own would not ordinarily demonstrate intended use. Thus, merely calling a product something besides “hearing aid” would not remove a product from device regulation under the FD&C Act if, for example, its labeling demonstrated that the product was intended to compensate for hearing loss.

C. History of This Rulemaking

Although this proposal is the first step in this rulemaking, FDA has taken other steps to initiate an update of the regulatory framework for hearing aids. Prior to the enactment of FDARA, FDA had considered means to improve access to hearing aids. For example, we considered a report on the public health implications of hearing loss in adults that made recommendations to improve affordability and accessibility of hearing aids and to foster innovative hearing aid technology. The October 2015 report by the President’s Council of Advisors on Science and Technology (PCAST) recommended, among other actions, that, “FDA should approve [a] class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser” (Ref. 7). In addition, the report concluded, among other things, that the Federal requirement for a medical examination, or a written waiver of such examination, “provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance” (Ref. 7).

Similarly, FDA, other Federal Agencies, and a consumer advocacy group co-sponsored a study entitled “Hearing Health Care for Adults: Priorities for Improving Access and Affordability” through the National Academies of Sciences, Engineering, and Medicine (NASEM). The resulting NASEM report, published on June 2, 2016, similarly recommends that FDA create a new category of OTC “wearable hearing devices” (using a term distinct from

⁴ Section 520(q)(1)(B) of the FD&C Act also specifically excludes from the definition of OTC hearing aids products intended to amplify sound for nonhearing impaired consumers in situations including hunting and bird watching.

“hearing aids”) and also that FDA remove the medical evaluation requirement for adults for hearing aids (Ref. 6). After a review of the literature and relevant clinical databases from the U.S. Department of Defense and the U.S. Department of Veterans Affairs, NASEM concluded that the health risk of missed diagnosis of treatable causes of hearing loss in adults is low, and “[the] regulation [requiring a medical examination or waiver] provides no clinically meaningful benefit, and the waiver presents a barrier to access with no substantial enhancement of patient safety.”

Both PCAST and NASEM provided recommendations regarding FDA Quality System requirements (which set forth requirements for good manufacturing practices or GMPs) for the proposed category of OTC hearing aids. PCAST stated the following:

FDA should exempt this class of hearing aids from QSR regulation in its present form and substitute compliance with standards for product quality and recordkeeping appropriate for the consumer-electronics industry, developed by an appropriate third-party organization and approved by FDA. Similar actions should be taken with respect to diagnostic hearing tests used to dispense and fit Class I hearing aids.

However, NASEM recommended that these devices “[b]e subject to quality system regulation (QSR) requirements, but be considered for exemption from certain QSR requirements as determined by FDA to be appropriate for this category.”

We held a public workshop on April 21, 2016, entitled “Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids,” (announced at 81 FR 784; see Ref. 9 for materials). FDA requested comments on several topics relating to hearing healthcare technology and improved access, including the appropriate level of GMP regulation (Quality System requirements) to ensure the safety and effectiveness of air-conduction hearing aid devices in consideration of the PCAST report recommendations.

FDA received hundreds of comments to the docket for this workshop prior to the (extended) deadline of June 30, 2016. In addition, 2 keynote speakers (from PCAST and NASEM), 12 invited speakers, and 24 public speakers offered comments or presentations at the workshop. Workshop speakers and submitters of docket comments were generally: healthcare

professionals (or healthcare professional organizations), members of industry, patients or consumers, academics, consensus standards developers, and science organizations.

Comments from this workshop ranged generally from strong opposition to strong support for the PCAST recommendations. Other comments were more nuanced. To summarize very broadly, all parties agreed that some combination of regulatory requirements and flexibility in compliance would provide reasonable assurance of safety and effectiveness. The differences in opinion lie in the preferred approach and its implementation to achieve these common goals. For example, some preferred amending the QS regulation and relying on inspections while others preferred allowing voluntary conformity to a consensus standard potentially relying on third-party certification.

In another effort to address the current regulatory framework, FDA also issued a guidance document, as noted above, related to the conditions for sale for air-conduction hearing aids. In that document, we announced our intent to reexamine and modify § 801.421 based on the PCAST and NASEM recommendations, as well as from other stakeholders, taking into consideration and addressing their recommendations as appropriate before adopting regulations for OTC hearing aids. The docket no. FDA-2016-D-3466 included commentary that expressed support for the creation of a “basic” category of hearing aids such as OTC hearing aids and provided recommendations for measures to support safe and effective use. We also received multiple telephone calls expressing similar interest in reducing regulatory burdens and questioning how the issuance of the guidance affected States’ requirements.

In developing this proposed rule, we considered the input and questions we have received on the guidance, as well as the comments from the April 2016 public workshop and the recommendations from PCAST and NASEM.

D. Incorporation by Reference

FDA is proposing to incorporate by reference the Method and tables for clause 4.1 of ANSI/CTA-2051, “Personal Sound Amplification Performance Criteria,” dated January 2017,

from the American National Standards Institute, 1889 L Street NW, 11th floor, Washington DC 20036; <https://www.ansi.org>, 202-293-8020. You may download the standard from the web at <https://webstore.ansi.org/standards/ansi/cta20512017ansi>. The Method and tables for clause 4.1 describe how to measure frequency response and include technical data for adaptations for different circumstances. The Method and tables would provide a standardized way to quantify frequency response for OTC hearing aids and meet the related proposed requirements (see section III.E.1).

FDA is also proposing to incorporate by reference ANSI/ASA S3.22-2014, “Specification of Hearing Aid Characteristics,” dated November 2014, from the American National Standards Institute, 1889 L Street NW, 11th floor, Washington DC 20036; <https://www.ansi.org>, 202-293-8020. ANSI/ASA S3.22-2014 describes tolerances and test methods used for certain measurements of hearing aid performance. The application of ANSI/ASA S3.22-2014 provides professional hearing aid fitters with standardized technical information to help them select the correct hearing aid and ensure optimal fit and performance for hearing aid users (see section III.H.2).

II. Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices, as defined in section 201(h) of the FD&C Act, intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) defines three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval) (see 21 U.S.C. 360c). Hearing aids are devices intended for human use and are subject to the FD&C Act. Currently, air-conduction hearing aids are generally either class I or class II devices.

FDARA amended the FD&C Act to apply requirements specific to certain hearing aids and defined the term “over-the-counter hearing aid” (see 21 U.S.C. 360j(q)). We are issuing these requirements for OTC hearing aids pursuant to section 709(b) of FDARA, which

authorizes FDA to establish requirements for labeling, output limits, conditions for sale and distribution of OTC hearing aids, and other requirements that provide for reasonable assurance of safety and effectiveness of these devices.

In addition, the FD&C Act provides that a device is misbranded unless, among other requirements, its labeling bears adequate directions for use (see section 502(f)(1) of the FD&C Act). Consistent with section 502 of the FD&C Act, FDA has issued regulations that exempt certain kinds of devices from the requirement for adequate directions for use. Section 502(f)(2) further requires adequate warnings against use of a device in those pathological conditions, or by children, where use of the device may be dangerous to health. The labeling must also bear adequate warnings against unsafe dosage or methods or duration of administration or application (see section 502(f)(2) of the FD&C Act). Such warnings must be in such manner and form as are necessary for the protection of the users (see section 502(f)(2) of the FD&C Act).

A device is also misbranded if its labeling is false or misleading in any particular (see section 502(a) of the FD&C Act). Section 201(n) of the FD&C Act states that in determining whether labeling or advertising is misleading, there shall be taken into account not only representations made or suggested but also the extent to which labeling or advertising fails to reveal material facts.

Other misbranding provisions under the FD&C Act would apply as well, including section 502(c), which deems a device to be misbranded if any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Additionally, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)). The proposals in this rulemaking

would be for the efficient enforcement of the FD&C Act because, if finalized, they will provide standards for the legal marketing of safe and effective hearing aid devices.

Violations of any final rules from this rulemaking, once in effect, would render the hearing aids adulterated and/or misbranded under sections 501 and/or 502 of the FD&C Act, and subject to enforcement action, for example, seizure (see section 304 of the FD&C Act (21 U.S.C. 334)), injunction (see section 302 of the FD&C Act (21 U.S.C. 332)), and criminal prosecution (see section 303 of the FD&C Act (21 U.S.C. 333)). Prohibited acts include, among others, introducing an adulterated or misbranded device into interstate commerce (see section 301 of the FD&C Act (21 U.S.C. 331)).

Under section 521 of the FD&C Act, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement that is different from, or in addition to, any requirement applicable under the FD&C Act to the device and that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FD&C Act (21 U.S.C. 360k). Section 521 of the FD&C Act also provides that FDA may grant an exemption from preemption under certain circumstances. Section 709(b) of FDARA also includes a preemption provision with respect to requirements for OTC hearing aids.

III. Description of the Proposed Rule

We are proposing multiple related actions in this rulemaking:

- Add to part 800, subpart B (21 CFR part 800, subpart B), definitions and other rules for OTC hearing aids;
- Remove § 801.420 and repeal § 801.421;
- Add to part 801, subpart H (21 CFR part 801, subpart H), § 801.422, labeling requirements for prescription hearing aids;

- Amend part 874, subpart D (21 CFR part 874, subpart D), in multiple places to update classification regulations for hearing aids and align hearing aid types by sound-conduction technology; and
- Amend part 808, subparts A and C (21 CFR part 808, subparts A and C), by updating the Scope and removing most of the current regulations codifying previous decisions for exemption from Federal preemption for certain States.

If this action is finalized, all non-OTC hearing aids will be prescription devices and would be subject to the labeling requirements in new § 801.422 as well as those in the existing § 801.109, but they would no longer be restricted devices. Note that a prescriber is any practitioner licensed by the law of the State in which the practitioner practices to use, or order the use of, the device. When the prescriber of a hearing aid need not be a physician, the labeling of a prescription hearing aid will describe other prescribers, for example, audiologists (see § 801.109(b)(1)).

We believe the proposed actions will, in combination, promote and protect the public health by, among other things, providing reasonable assurance of safety and effectiveness of OTC and prescription hearing aids. These actions would also help minimize the complexity of the applicable regulations, if finalized, through organization. We are proposing to add the OTC Hearing Aid Controls to 21 CFR part 800, subpart B, entitled “Requirements for Specific Medical Devices,” which would make them easy to locate. Labeling requirements for prescription devices would remain in part 801, Labeling, subpart H, “Special Requirements for Specific Devices.” Table 2 outlines the proposed hearing aid rules. Section III.I summarizes the proposed revisions to part 808.

Table 2.--Outline of Proposed Hearing Aid Rule

800.30	801.422	874.3301	874.3305
Over-the-Counter Hearing Aid Controls ¹	Prescription Hearing Aid Labeling ¹	Bone-Conduction Hearing Aid	Air-Conduction Hearing Aid

<ul style="list-style-type: none"> (a) Scope (b) Definitions (c) Labeling <ul style="list-style-type: none"> • Package • Labeling Inside the Package • Labeling on the Device • Technical Specifications (d) Output Limits (e) Electroacoustic Performance <ul style="list-style-type: none"> • Distortion Control • Self-generated Noise • Latency • Bandwidth • Smoothness (f) Design Requirements <ul style="list-style-type: none"> • Insertion Depth • Atraumatic Materials • Proper Fit • Tools, Tests, or Software (g) Condition for Sale (h) Effect on State Law (i) Incorporation by Reference 	<ul style="list-style-type: none"> (a) Scope (b) Definitions (c) Labeling <ul style="list-style-type: none"> • Package • Labeling Inside the Package • Labeling on the Device • Technical Specifications • Misbranding (d) Incorporation by Reference 	<ul style="list-style-type: none"> (a) Identification (b) Classification <p>Product codes LXB, MAH</p>	<ul style="list-style-type: none"> (a) Identification (b) Classification <ul style="list-style-type: none"> • Legacy • Wireless • Self-Fitting <p>Product codes ESD, OSM, QDD, LRB, and LDG</p>
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¹ These requirements would apply in addition to all other applicable requirements, including applicable labeling requirements in parts 801 and 830 (21 CFR parts 801 and 830). For example, for prescription devices, the labeling requirements in § 801.109 would continue to apply in addition to new § 801.422.

A. Scope (Proposed § 800.30(a))

The regulation would clarify which devices are subject to the OTC Hearing Aid Controls. Among other changes, FDARA amended the FD&C Act to define the term “over-the-counter hearing aid,” and section 709 of FDARA directs FDA to establish certain requirements for labeling, output limits, conditions for sale, and other requirements that provide reasonable assurances of the safety and effectiveness of OTC hearing aids. We propose to call this set of requirements “Over-the-Counter Hearing Aid Controls” and add § 800.30 to establish the OTC category of hearing aids and their requirements.

The scope, proposed paragraph (a), would specify the devices to which the regulation would apply, assisting with the determination of applicable requirements. This provision clarifies that a hearing aid is either in the prescription or OTC category and that, regardless of category,

special controls found in the applicable classification regulation and other requirements in the FD&C Act apply.

B. Definitions (Proposed §§ 800.30(b) and 801.422(b))

FDA proposes to include the definition of an OTC hearing aid, consistent with the definition in section 520(q)(1) of the FD&C Act, and the definitions of other terms integral to understanding § 800.30. In several cases, we are proposing parallel definitions (sometimes slightly modified) under the proposed requirements for prescription hearing aid labeling in § 801.422.

Defining hearing aids. FDARA authorizes controls for devices that, among other characteristics, use the same fundamental scientific technology as air-conduction hearing aids under §§ 874.3300 or 874.3305. Section 520(q)(1)(A)(i) of the FD&C Act does not specifically refer to § 874.3325 because, at the time of FDARA's enactment, FDA had not classified that device type. However, we consider self-fitting hearing aids currently classified under § 874.3325 to be eligible for regulation as OTC hearing aids.

We consider them as such because, although self-fitting hearing aids under § 874.3325 differ from hearing aids under §§ 874.3300 and 874.3305 in that they incorporate technology, including software, that allows users to program their hearing aids, self-fitting hearing aids use the same air-conduction technology as hearing aids under §§ 874.3300 and 874.3305. Self-fitting hearing aids also meet the other elements of the OTC hearing aid definition in section 520(q)(1)(A) of the FD&C Act. For example, self-fitting hearing aids, through tools, tests, or software, allow the user to control the hearing aid and customize it to the user's hearing needs (see section 520(q)(1)(A)(iii) of the FD&C Act).

The proposed definitions of "hearing aid" (which is the current definition), "air-conduction hearing aid," "over-the-counter hearing aid," and "prescription hearing aid" help to

delineate the different device categories.⁵ As stated in section 520(q)(1)(B) of the FD&C Act, the definition of “over-the-counter hearing aid” does not include PSAPs. Similarly, the definition of “hearing aid” more generally excludes PSAPs that are not intended to aid with or compensate for impaired hearing. The proposed definition of “prescription hearing aid” in proposed § 801.422 is the same as that in the OTC Hearing Aid Controls except that the definition for prescription devices would cross-reference the OTC Hearing Aid Controls, proposed § 800.30.

Defining licensed persons. In that vein, OTC hearing aids will be available without the supervision, prescription, or other order, involvement, or intervention of a licensed person (section 520(q)(1)(A)(v) of the FD&C Act). A definition of “licensed person” would help delineate that a patient or consumer of OTC hearing aids will not need to consult an audiologist, a physician, or other licensed person prior to or after purchasing an OTC hearing aid. The proposed definition of “licensed person” also clarifies that FDA interprets “licensed person” to include businesses consistent with the broad definition of “person” in section 201(e) of the FD&C Act. For example, OTC hearing aids may be available for sale from businesses that are not specially licensed to distribute OTC hearing aids.⁶

FDA does not interpret section 520(q)(1)(A)(v) of the FD&C Act or section 709(b) of FDARA as preempting a State’s ability to establish or continue in effect generally applicable State business or professional licensing requirements. In general, such requirements would not be “specifically related to hearing products,” so they are not subject to section 709(b)(4) of FDARA. If a person purports to be a licensed professional or business, then a State could regulate the person as such. Thus, for example, a person identifying as an “audiologist” would be subject to State professional or facility licensure requirements because an audiologist is a licensed professional.

⁵ Although some have suggested the use of a different name for OTC hearing aids, for example, a “wearable,” we are proposing to continue referring to them as hearing aids to maintain consistency with the device type classifications and section 520(q) of the FD&C Act.

⁶ See section III.G, discussing the codification of the preemption provision, section 709(b)(4) of FDARA.

However, unlike identifying as an “audiologist,” some descriptions for professions do not on their own imply licensure in relation to OTC hearing aids. Section 709(b)(4) of FDARA lists certain activities that may be undertaken with respect to OTC hearing aids without the supervision, prescription, or other order, involvement or intervention of a licensed person. FDARA specifically lists the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids. (For convenience, we will refer to these activities collectively as “commercial activity” in this document.) Thus, a person representing as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) of OTC hearing aids would not be a “licensed person” for the purposes of § 800.30 solely for that reason. Nor could a State require such persons to undertake special licensing or equivalent activities. In contrast, a person voluntarily identifying, for example, as a “licensed dispenser” (i.e., not just a “dispenser”) would be subject to corresponding State requirements for such dispensers to the extent that the State requirements do not restrict or interfere with commercial activity involving OTC hearing aids (see section 709(b)(4) of FDARA).

The proposed definition of “licensed person” specifies the descriptions of profession, consistent with section 709(b)(4) of FDARA, that would not, on their own, imply licensure relating to OTC hearing aids. Section III.G of this document describes other preemption scenarios in addition to licensed persons.

Defining tools, tests, or software. Another element of the definition of OTC hearing aids requires that users be able to control or customize the devices through tools, tests, or software (see section 520(q)(1)(A)(iii) of the FD&C Act). We interpret this requirement to refer to the ability for a layperson to perform such activities. As such, the proposed definition of “tools, tests, or software” clarifies that OTC hearing aids are those devices that allow lay users to control the device and customize it, such as the device’s output, to meet their individual hearing needs.

Other definitions. The proposed definition of “used hearing aid” in both the OTC and prescription device provisions clarifies which hearing aids would be subject to certain proposed

labeling requirements for used or rebuilt hearing aids. The proposed definitions are the same for OTC and prescription hearing aids, and they are derived from the current definition in § 801.420 except that we have revised the wording for clarity.

The proposal for prescription hearing aid labeling in § 801.422 retains the definition for “dispenser” that is currently applicable to all hearing aids. However, we propose to revise the wording to clarify that the definition applies only for purposes of prescription hearing aid labeling and propose other clarifying revisions to track the definition of “person” in section 201(e) of the FD&C Act more closely. We believe the definition will continue to be useful because the proposed requirements for prescription hearing aids refer to the dispenser.

FDA welcomes comments on the definitions pertinent to the regulation of OTC hearing aids (as well as any other portion of this proposal). In particular, we seek comments on the clarity of the definitions and ways to improve the definitions to encourage and support the broad availability of safe and effective devices.

C. Labeling (Proposed § 800.30(c))

We are proposing labeling requirements to provide consumers with essential information for the safe and effective use of OTC hearing aids. Section 709(b)(2)(C) of FDARA specifically directs FDA to include, among appropriate labeling requirements, a conspicuous statement that the device is only intended for adults age 18 and older, information on how consumers may report adverse events, information on any contraindications, conditions, or symptoms of medically treatable causes of hearing loss, and advisements to consult promptly with a licensed healthcare practitioner. In addition, section 709(b)(2)(A) of FDARA directs FDA to establish requirements that provide reasonable assurances of the safety and effectiveness of OTC hearing aids, and we intend the proposed labeling requirements to do so.

In considering which statements to require, we note the important role of information in supporting broader use of OTC hearing aids. As part of the 2016 FDA hearing aid workshop, the Hearing Loss Association of America presentation stressed the importance of clear labeling to

inform consumers so that the consumer “is empowered and knows what they’re buying and knows the limitations and what’s possible” (Refs. 9 and 10). FDA agrees, and we have proposed labeling requirements to empower consumers.

Further the proposed conspicuous statement that OTC hearing aids are intended for people age 18 years and older is necessary because the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people. Whereas hearing loss in older adults is most commonly related to noise exposure and aging, the etiology (causes) of hearing loss in younger people is varied and may result from conditions that warrant prompt diagnosis to avoid serious risks to health. These conditions may not be readily apparent and can include, but are not limited to:

- Congenital malformations (present since birth) of the external, middle, or inner ear;
- Infections, for example, otitis media (an inflammation of the middle ear) or congenital infections;
- Genetic causes, including hereditary syndromes that can involve cardiac, ophthalmic, renal, neurologic, and other organ systems (that is, syndromes that can involve the heart, eyes, kidneys, nerves, and other organs); or
- Certain exposures, for example, lead poisoning, hyperbilirubinemia (a buildup of a metabolic byproduct, bilirubin, in the blood), and drug ototoxicity (a toxic effect on the ear or its nerves).

The use of a hearing aid to treat hearing loss related to these conditions, without a medical evaluation, may delay diagnosis and treatment of the underlying condition. Further, prompt diagnosis is critical because, left untreated, these conditions may worsen, with potentially lifelong, adverse health effects. Because the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people, the proposed conspicuous statements are appropriate and provide reasonable assurance of safety and effectiveness of OTC hearing aids.

The proposed labeling provisions include requirements for labeling on the package and inside the package, along with requirements for labeling on the device itself. These requirements would apply in addition to all other applicable labeling requirements in, for example, parts 801 and 830. In any of the labeling, manufacturers could continue to include additional truthful, non-misleading information provided it does not conflict with other requirements (such as those mentioned above).

In proposing where to place labeling statements--on the package or inside the package--we have considered when users, prospective users, and others should become aware of information (before or after purchase). We have also considered the limited space available on the packaging as well as simplicity of format.

FDA welcomes your comments on the proposed labeling requirements, including the placement or conspicuousness of statements, as well as whether the statements are clear and understandable. For example, in reviewing the proposals, did you find important information quickly? Did you find the information clear and easy to understand? We are particularly interested in your feedback about phrasing or formatting to convey information to people who are anticipated users, or more generally, who are not hearing health professionals. A rationale or evidence would make your feedback more useful. For example, if a proposed statement is unclear, telling us why is generally more helpful than saying only that you find the statement to be unclear.

1. Package Labeling

We are proposing that the outside of the package include information that consumers would need to know prior to purchasing the device, such as who is a candidate for the device, how to determine if you are a candidate, and when to seek professional help before trying the device. We believe this information empowers consumers and answers threshold questions about the suitability of purchasing an OTC hearing aid for their hearing needs. This proposal would

also emphasize who the intended user is, to reduce the likelihood that people younger than 18 would purchase or use an OTC hearing aid.

To summarize, the proposed statements on the package describe:

- A conspicuous warning that the device is not for users younger than 18 years old;
- The symptoms of perceived mild-to-moderate hearing loss;
- Considerations for seeking a consultation with a hearing healthcare professional; and
- Red flag conditions: warnings to consumers regarding signs and symptoms that should prompt a consultation with a licensed physician (preferably an ear specialist).

However, we are not proposing to require other information on the package, for example, mobile operating system compatibility or whether the package contains the necessary batteries. Further, we are proposing language that accurately conveys information to readers without relying on specialized knowledge (i.e., for laypeople). We welcome your comments on whether to require other information on the package labeling and whether you had any difficulty understanding the information (and if so, your suggestions for improvements).

a. Symptoms suggesting perceived mild to moderate hearing loss. Prospective users may not know their definitive degree, configuration, or etiology of hearing loss. That is, they may not know the exact nature or cause, so commenters for the public meeting discussed various ways to communicate the signs of perceived mild to moderate hearing loss and reasons to seek medical evaluation. They generally agreed that such information should appear on the outside of the package. We agree with this sentiment and are proposing that the information be readily apparent prior to purchase to help people to determine whether an OTC hearing aid may benefit them.

To that end, we are proposing four scenarios that a person may recognize (symptoms) that suggest perceived mild to moderate hearing loss. We have selected these scenarios because they commonly present difficulties to people with perceived mild to moderate hearing loss and are situations in which users are likely to benefit from the use of OTC hearing aids. We have also based the selection on stakeholder input from the public workshops. Although people with

normal hearing may sometimes experience these scenarios, people with perceived mild to moderate hearing loss will experience them more frequently, if not regularly. We have phrased the information to emphasize that the device is intended for people who are 18 or older, and the phrasing avoids medical and technical terms while describing everyday situations.

b. Considerations for seeking consultation with a hearing healthcare professional.

However, because a prospective user may have hearing impairment beyond, or different from, perceived mild to moderate hearing loss, we are proposing a statement to assist people in evaluating the potential for increased benefit from an OTC hearing aid. We believe this information is important, and have titled it as such, and appropriate for users and prospective users who are not familiar with hearing aids.

c. “Red flag” conditions. In that vein, we are proposing to continue to require a statement advising users and prospective users to seek medical care if they exhibit any one of a number of conditions. We are not modifying the list of conditions from its present form except for phrasing and formatting changes to improve readability, as well as a change to the time periods (from 90 days to 6 months). We intend the change to the time periods to encourage consumers to consider a longer personal history, which may help them to identify the conditions without the involvement of a licensed person. The list includes reliable indicators of the possibility of an underlying medical condition that a hearing aid cannot treat. For example, fluid, pus, or blood coming out of the ear may indicate an active infection, as could sudden, quickly worsening, or fluctuating hearing loss. An examination by a physician, preferably an ear specialist, would determine whether such an underlying condition is present and treatable, potentially halting or reversing hearing loss.

d. Other information. We are also proposing to require that the outside package include a web address and telephone number for consumers to access a digital copy or request a paper copy of all labeling, including the labeling inside the package, for that OTC hearing aid. A

website could provide easy access to the more comprehensive information found in the labeling inside the package and could allow the use of other media to convey information.

FDA is proposing to require that this labeling be available online or be able to be requested by phone prior to purchase to facilitate product familiarity to make a purchasing decision. We believe having the information found inside the package will help prospective users choose a safe and effective device without the involvement of a licensed person. As proposed, this information would be available without the need for consumers to register for access, for example, by registering for a website member login.

Further, a download page could include, but would not be required to include, additional resources, for example, video explanations or tutorials to aid prospective users in selecting and using a device, as well as a mechanism for reporting complaints or adverse events. Since such additional resources would not be required under this proposal, accessing such resources could entail, for example, registering as a website member.

Please note that we are not proposing to require the distribution of paper copies for all OTC hearing aids because an analogous provision in the Hearing Aid Restrictions yielded little benefit--very few people requested a review of the paper copy--while adding to the regulatory burden. We are seeking comment on these proposed requirements (and any other portion of this proposed rule) regarding equitable access to the information and/or OTC hearing aids.

We are also proposing to require that the manufacturer disclose its return policy or, if none, state that it does not accept returns. Such a requirement would be appropriate, because prospective users of OTC hearing aids may be unsure whether an OTC hearing aid will meet their hearing needs. If an OTC hearing aid does not meet a user's hearing needs, the user may leave the device in the "dresser drawer." (This is a common description of the phenomenon of relegating the device to disuse--putting it away, never to use it again--and foregoing the potential benefit of a more-satisfactory device). Thus, a statement of the return policy would be appropriate because, without the services of a licensed person, some users may be more

dependent on the manufacturer's return policy (as opposed to the licensed person's) to avoid leaving an OTC hearing aid in the dresser drawer. A statement of the return policy would provide appropriate information to prospective users to help them determine the suitability of options given individual circumstances and preferences such as budget and willingness to try multiple OTC hearing aids. Additionally, consistent with the existing hearing aid requirement in § 801.420(c)(5), we are proposing that, when an OTC hearing aid is used or rebuilt, the outside package declare that fact. These requirements would advance the public health by facilitating the purchase of devices that meet users' hearing needs.

We are not proposing to require that manufacturers accept returns under these proposed Federal regulations. However, we likely would not consider a generally applicable State or local requirement to accept returns (i.e., the requirement applies to any product) as a requirement specifically related to hearing products. Further, we believe that a State or local requirement for retailers (persons who sell to end users) to accept returned OTC hearing aids would likely promote--rather than restrict or interfere with--commercial activity involving the devices by reducing the financial risk to purchasers. As such, generally, State or local requirements for returns would continue to apply provided they do not conflict with the final rule based on this rulemaking. We are seeking comment on whether such a State or local requirement would promote, rather than restrict or interfere with, commercial activities involving OTC hearing aids.

Participants at the June 9, 2017, NASEM public workshop generally agreed with the importance and utility of requiring certain information on the package. Participants discussed potential labeling requirements such as these for OTC hearing aids (see Ref. 11). Numerous participants focused on the signs and symptoms of consumers who have mild-to-moderate hearing loss and might potentially benefit from OTC hearing aids. Specifically, participants expressed concerns that consumers would need information to help decide whether to purchase the products and/or whether to seek professional services. The proposed requirements in this document have taken these comments into account.

2. Labeling Inside the Package

We are proposing to require that manufacturers place labeling inside of the package with the information that consumers will need after purchasing an OTC hearing aid for its safe and effective use. The proposed content of this labeling includes:

- Warnings, cautions, and notes, including a conspicuous statement warning against the use of the OTC hearing aid in people younger than 18 years old as well as a warning regarding “red flag” medical conditions to prompt consumers to consult with a licensed physician and a note about how to report adverse events to FDA;
- Illustration(s) of and information about the controls, user adjustments, and the battery compartment;
- A description of any accessory that accompanies the OTC hearing aid;
- Adequate directions for use, consistent with § 801.5 (21 CFR 801.5), including but not limited to information on sizing and inserting the eartip as well as the tools, tests, or software that allow the user to control and customize the OTC hearing aid to the user’s hearing needs (e.g., to self-select, self-fit, and self-check the performance of the device);
- Technical specifications to allow users, prospective users, and others to evaluate and compare the performance of OTC hearing aids;
- Description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid;
- Identification of known physiological side effects associated with using the OTC hearing aid that may warrant consultation with a physician, including but not limited to skin irritation and accelerated build-up of ear wax (cerumen accumulation);
- Information on repair services; and
- If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

We believe these labeling requirements for OTC hearing aids will help provide reasonable assurance of safe and effective use of OTC hearing aids for consumers with perceived mild-to-moderate hearing loss. We intend the proposed labeling requirements to provide lay consumers with adequate information, in particular, to ensure that those purchasing OTC hearing aids know when to seek professional intervention, how to use the device safely and effectively, and where and how to obtain additional information or assistance. The 2016 NASEM report supports FDA’s proposal in that it similarly recommends that OTC hearing aids “[i]nclude thorough consumer labeling, including information on:

- frequency gain characteristics;
- adequate directions for use;
- communication challenges for which it may be helpful to seek professional consultation; and
- medical situations, symptoms, or signs for which to consult with a physician” (Ref. 6).

We agree that thorough consumer labeling will assist users, potential users, and others with selecting, fitting, and wearing OTC hearing aids. Even so, the proposed requirements in this rulemaking are not intended as a substitute for other FDA regulations. Thus, for example, if adequate directions for use were to require additional information beyond that proposed in this rulemaking, manufacturers would need to include that additional information (see § 801.5 regarding adequate directions for use).

As for the NASEM report’s recommendations for OTC hearing aids regarding information about communication challenges and medical indicators, we agree that such information will help provide reasonable assurance of safety and effectiveness, and we have included that information, as well as the full-on gain value in our proposed labeling requirements. (Gain is a measure of amplification, and its full-on value is its maximum. We provide an explanation of gain in section III.D.2.)

We are not proposing to require additional technical information in the labeling for OTC hearing aids other than those in proposed § 800.30(c)(4); however, the labeling may optionally include such information if desirable. For example, technical information similar to what is currently required for all hearing aids may be useful in assisting audiologists offering services to users (see § 801.420(c)(4)). Multiple stakeholders voiced a similar view during the 2016 FDA workshop (Refs. 9, 10, and 12). Some added that scientific or technical information (in addition to the information we are proposing to require for OTC hearing aids) may be meaningful for consumers to make their decisions, especially if they are familiar with the technology. Although such additional information may be desirable for some consumers, FDA does not believe it is necessary to assist consumers in their selection.

FDA intends to issue at a later date a separate comprehensive guidance document that discusses, in part, labeling information and communicating that information with the goals of increasing transparency and choice to consumers. In accordance with 21 CFR 10.115, we will announce the availability of the draft of that guidance separately from this rulemaking, and the announcement will include information for submitting comments about that guidance, which will be separate and distinct from comments for this rulemaking. We do not intend to consider comments submitted to the docket for this rulemaking unless they pertain to the proposals in this document.

3. Labeling on the Device Itself

We are proposing to require that the labeling on the device itself include the serial number and symbol(s) for proper battery insertion orientation when applicable. If the device has been used or rebuilt, a tag indicating such would have to be physically attached to the device in addition to the statement on the outside of the package.

D. Output Limits (Proposed § 800.30(d))

FDA is proposing a maximum acoustic output limit requirement for an OTC hearing aid to provide reasonable assurance of safety and effectiveness. Section 709(b)(2)(B) of FDARA

directs FDA to establish or adopt output limits appropriate for OTC hearing aids. A high output can be unsafe and further impair hearing. However, too low an output reduces device effectiveness and can lead to poor device performance, including clipping and distortion. In turn, poor performance would reduce consumer satisfaction and use of the devices. We believe that the proposed output limits balance the above considerations for these devices, so the limits are therefore appropriate for OTC hearing aids.

1. Overview of Proposed Output Limits

We propose a maximum OSPL90 output level of 115 dB sound pressure level (SPL) as a general rule to balance consumer safety with device performance.⁷ However, we would permit a limit of 120 dB SPL for an OTC hearing aid that implements input-controlled compression and a user-adjustable device volume control (i.e., volume adjustment). This is because a user-adjustable volume control allows the user to reduce the output below the maximum, in effect, further reducing the device's limit. Input-controlled compression is an automatic function that dynamically reduces the output of frequency ranges based on the input. Both of these design features thus reduce the likelihood that a user will experience high acoustic outputs, at the device's limit, at any given moment. Relatedly, we are proposing that the device labeling state the value of the maximum OSPL90 level (see section III.C.1).

We have proposed output limits to prevent injuries from exposure to loud sounds when amplified by OTC hearing aids while still allowing a sufficient dynamic range of outputs, called "headroom," to provide effective amplification for users with perceived mild to moderate hearing loss. A device without sufficient headroom (when the output limit is too low) would not be as effective as a device with a higher output. However, a device with too high an output limit could further worsen hearing impairment.

⁷ OSPL90 is an abbreviation for the sound output as measured in a standardized way. ANSI/ASA S3.22-2014 defines it as the SPL developed in the specified 2-cm³ earphone coupler when the input SPL is 90 dB with the gain control of the hearing aid full-on. To simplify, this describes a way to simulate amplifying a sound into the ear canal, providing a standardized measurement for the amplified output.

2. Data and Stakeholder Perspectives on the Proposed Output Limit

We base the proposed limits on physiological data and stakeholder input, some of which appear in Clause 4.3 of ANSI/CTA-2051, a voluntary consensus standard (Ref. 13). Note that, although ANSI/CTA-2051 is a consensus standard for PSAPs, we believe that this standard is also relevant for OTC hearing aids, which provide personal sound amplification, albeit for purposes of aiding with or compensating for impaired hearing. The standard's basis for the output limit is a national workplace safety guideline, *Occupational Noise Exposure*, from the National Institute for Occupational Safety and Health (NIOSH) (Ref. 14). NIOSH developed this standard, which we will refer to as NIOSH-98, to define permissible exposure time depending on the intensity of the sound.

In general, the relationship between the loudness (SPL) and the time before damage to hearing is inversely related: the louder the sound, the shorter the time before hearing damage. Above about 85 dBA (A-weighted decibels), the exposure time is cut in half for every 3 dB increase in sound level (Ref. 14).⁸ Thus, the difference between recommended exposure times for 115 dB SPL and 120 dB SPL is approximately 61 seconds, where 115 dB SPL provides approximately triple the permissible exposure time than 120 dB SPL (see the next section for a more detailed explanation of the “3-dB exchange rate”).

Appendix A of ANSI/CTA-2051 describes this tradeoff between output level and exposure time, providing a rationale for a maximum OSPL90 output limit of 120 dB based on NIOSH-98. For the purposes of that standard, NIOSH found that 115 dBA SPL is acceptable for up to about 30 seconds. ANSI/CTA-2051 explains that this allows the user sufficient time to turn off or remove the hearing aid before the exposure becomes unacceptably dangerous to hearing

⁸ Weighting sound levels means that different frequency ranges have different values (weights) added or subtracted to them, so for example, lower frequencies may receive more weight than higher frequencies for the purpose of expressing the sound level. Different sets of weighting values have different purposes. A-weighting tries to account for the fact that the human ear is less sensitive to lower frequencies, which generally do not sound as loud to people as higher frequencies at the same SPL. Therefore, A-weighted decibels can be useful to express how a listener might perceive a sound level when considering the ear's variable sensitivity to different frequencies. This weighting method is common but is not the only one that accounts for human hearing perception. C-weighting is another.

ability. ANSI/CTA-2051 observes that sound levels of desirable, “real-life sonic events” can approach the NIOSH-98 level, for example, a live symphony in which a user would want to experience “occasional peaks” undistorted. However, a lower output limit would not allow enough headroom for a faithful reproduction of such peaks and would lead to output clipping or distortion. Thus, a limit that allows desirable peaks, but sufficient time to react to undesirably loud sounds, would be ideal. As ANSI/CTA-2051 explains, 115 dBA is equivalent to an OSPL90 value of approximately 120 dB SPL with an allowance of 28 seconds to react.

FDA agrees that an OTC hearing aid should provide sufficient headroom to amplify relatively loud sounds such as those in a symphony, yet the device should not have an output so high that the user does not have time to act before sustaining injury. Further, the output should not be consistently at a limit of 120 dB SPL, accomplished through the inclusion of input-controlled compression and user-adjustable volume control.

In addition to considering the ANSI/CTA and NIOSH standards supporting the proposed limits, we considered stakeholder input. On June 9, 2017, NASEM held a public workshop meeting where participants discussed, among other topics, a 120-dB SPL maximum output limit for an OTC hearing aid (see Ref. 11). Numerous speakers commented that an OSPL90 output limit somewhat lower than 120 dB SPL for OTC devices would likely still provide sufficient amplification and headroom for individuals with perceived mild to moderate hearing loss while providing a safety margin in terms of sound-intensity exposure.

Additional comments during the NASEM workshop raised the importance of input-controlled compression and the inclusion of a user-adjustable volume control in order to help reduce overamplification. Each of those features can limit the device’s output by dynamically reducing device gain as the input level increases, thus increasing the safety profile of a device: The user generally would not be listening at louder output levels as often as would occur without these features.

FDA has also reviewed numerous public comments on the risk of harm from excessive output, stemming from our 2016 public workshop, Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids (see Refs. 9, 15, and 16). We agree that excessive amplification from OTC hearing aids could pose a risk to individuals' health and thus are proposing that the maximum output (OSPL90) of OTC hearing aids not exceed a certain value, depending on device design features, that would provide users enough time to react to loud sounds to prevent injuries.

Some stakeholders have suggested inclusion of gain limits for OTC hearing aids. Gain is a measurement based on the ratio between the output and the input or, to simplify further, how much the device amplifies (or reduces) the input. A gain limit would further reduce the maximum device output because the device would sometimes reach the gain limit, providing no further amplification, before it reached the output limit. We are proposing not to limit the device gain because we believe that the proposed maximum output limit (together with the other proposed requirements) will provide reasonable assurance of safety and effectiveness without limiting the device gain also.

Moreover, a gain limit may unduly constrain the design of effective devices. Appropriate gain characteristics can depend on the implementation of the amplification circuit design (e.g., linear amplification versus wide dynamic range compression). Thus, appropriate gain settings for one device may not be appropriate for another device of a different design. We believe that allowing flexibility in the gain settings will help maximize the effectiveness of the particular circuit design a manufacturer implements for a device to address perceived mild to moderate hearing loss. In light of this, and since a maximum output limit would also in effect limit gain, we do not believe a separate, additional gain limit is necessary to provide reasonable assurance of safety and effectiveness. We also note that the NASEM report does not recommend any limit on gain for OTC devices, only on maximum output (Ref. 6).

3. The Proposed Output Limit Requirements Help Provide Reasonable Assurance of Safety and Effectiveness

In further consideration of user-adjustable volume controls and input-controlled compression, we believe that these two design features together will sufficiently mitigate the risk of a higher maximum output limit (from 115 dB SPL up to and including 120 dB SPL) by reducing the likelihood that the user will experience excessive sound levels for periods long enough to sustain damage to hearing (Ref. 14). Input-controlled compression such as wide dynamic range compression is also associated with hearing performance benefits in realistic environments that have varying levels of sound intensity for persons with mild-to-moderate sensorineural hearing loss (see, e.g., Refs. 17 to 21). That is, besides reducing the device's effective output limit, input-controlled compression also generally helps users hear better in daily situations.

In reaching this proposal on output limits, we note that hearing aids, including OTC hearing aids, are intended to be worn during all waking hours in a wide variety of listening environments and situations. Thus, user comfort is relevant to safety and effectiveness, and input-controlled compression and user-adjustable volume control increase comfort by dynamically adjusting gain and keeping outputs lower. This contributes to effectiveness and user satisfaction because users are generally more willing to wear a comfortable device consistently, maximizing the benefits of the device and the impact on public health.

We are not proposing to require input-controlled compression and a user-adjustable volume control for all OTC hearing aids, however. Thus, devices that do not have both of these features (which, in effect, reduce the device's output limit) would have to respect a 115 dB SPL limit, which would more than triple the safe exposure time compared to a 120 dB SPL limit (Ref. 14).⁹ Users would have ample time to take appropriate action to mitigate unacceptably high

⁹ Based on the 3-dB exchange rate--above 85 dB SPL, the time halves for each 3-dB increase--of Clause 1.1.1 of NIOSH-98, which is used by ANSI/CTA-2051, exposure to 115 dB SPL is $2^{(6/3)}$ or 3.17 times the ANSI/CTA-2051 recommended exposure limit of 28 seconds for 120 dB SPL, equaling approximately 89 seconds.

sound levels, for example, by adjusting the volume (if the device has a user-adjustable volume control), turning the device off, removing the device from the ear, or moving out of the loud environment. As noted above, the device labeling would also be required to include a reminder to consumers that, if they are in a loud listening environment that warrants hearing protection, they should remove their hearing aid(s) and use hearing protection.

To summarize, we believe that a 115 dB SPL output limit would help provide reasonable assurance of safety and effectiveness for the intended population. However, we acknowledge that 120 dB SPL could have additional effectiveness potential in certain circumstances, for example, when listening to a symphony by a live orchestra (Ref. 13). As discussed above, we believe that achieving that potential would be safe only if the device also includes input-controlled compression and a user-adjustable volume control. Overall, we believe this device-design contingent proposal for output limits helps provide reasonable assurance of safety and effectiveness of OTC hearing aids while providing ample design space for innovation.

E. Other Requirements (Proposed § 800.30(e) and (f))

Although certain labeling and output limits are necessary for reasonable assurance of safety and effectiveness of OTC hearing aids, these requirements alone are not sufficient to do so. FDA is therefore proposing that the devices must meet certain performance and design requirements in order to help provide reasonable assurance of safety and effectiveness, pursuant to section 709(b)(2)(A) of FDARA.

1. Electroacoustic Performance Requirements to Help Provide A Reasonable Assurance of Safety and Effectiveness

We are proposing to establish electroacoustic performance requirements to help ensure that the output of an OTC hearing aid safely and effectively compensates for perceived mild to moderate hearing loss in people age 18 and older. Electroacoustic performance describes how well a hearing aid converts an electrical signal, either digital or analog, into a sound (acoustic energy) or vice versa. Currently, hearing aid labeling must include technical data for certain

performance characteristics gathered according to the test methods specified in ANSI/ASA S3.22-2003 (see § 801.420(c)(4)). We do not believe, however, that the data that conform to ANSI/ASA S3.22 are adequate for consumers to select their own hearing aid without the supervision, involvement, or intervention of a licensed person (among other reservations).

This is because ANSI/ASA S3.22 does not specify any minimum performance requirements. Instead, it specifies tolerances, which are acceptable ranges of deviation from manufacturer-stated specifications. The manufacturer, not a standard, determines how the hearing aid performs. As a result, achieving optimal hearing aid performance currently depends in part on interpreting the technical data supplied by the manufacturer for selection and adjustment. The interpretation of this information is highly technical, so the information is useful to a professional but generally not the lay user.

For OTC hearing aids, we believe that the devices must meet certain electroacoustic performance specifications so that any OTC hearing aid would perform safely and effectively for perceived mild to moderate hearing loss after the user customizes the device for individual needs. To that end, we are proposing to use several applicable specifications for device performance from ANSI/CTA-2051 for OTC hearing aids. A device that met these performance specifications would safely and effectively reproduce sounds without the need for professional involvement.

Specifically, an OTC hearing aid should provide amplification with high fidelity so that the user can accurately perceive daily social and environmental sounds. High-fidelity (accurate) output means that the device reproduces the input frequencies clearly, without distortion and without undue frequency shaping. We believe such an OTC hearing aid will have certain performance characteristics to achieve fidelity: the OTC hearing aid would have sufficiently low distortion, would not introduce excessive self-generated noise or time delays between input and output, and would provide a sufficient frequency response bandwidth and smoothness. An OTC

hearing aid would have to achieve these, after customization to the individual's hearing needs, without the intervention of a licensed professional; that is, by design.

We have reviewed ANSI/CTA-2051:2017, which includes specifications for electroacoustic performance, and we believe that performance requirements based primarily on its Category 1 specifications would help provide reasonable assurance of safety and effectiveness of OTC hearing aids.¹⁰ These specifications relate to the device's processing of the input sound (the sounds detected by the device) to generate the output sound (the amplified sound that the device produces to assist the user). To summarize, FDA believes that the specifications that would help provide reasonable assurance of safety and effectiveness, as well as set an objective baseline for device performance, are:

- Distortion control limits;
- Self-generated noise limits;
- Latency limit;
- Frequency response bandwidth; and
- Frequency response smoothness limits.

We believe that the above listed electroacoustic requirements would ensure that an OTC hearing aid can accurately reproduce daily speech and other environmental sounds without the need for professional involvement. We believe that this performance level is requisite for the device to meet the needs of people with perceived mild to moderate hearing loss. Likewise, the performance requirements would help ensure that undesirable effects (such as distortion) do not impair safety and effectiveness.

ANSI/CTA-2051 is, to FDA's knowledge, the first voluntary consensus standard to describe performance characteristics for hearing amplifiers (as opposed to standardized test methods and tolerances). Upon reviewing the voluntary consensus standard, and in consideration

¹⁰ Note that the consensus standard includes a maximum acoustic output as a Category 1 specification; however, we are proposing a different maximum output level rather than the consensus standard's (see section III.D). Additionally, we are proposing a latency limit, which the standard includes as a Category 2 specification.

of related presentations during FDA's 2016 hearing aid workshop, we believe that the rationale and methodology of the standard are sound, and we believe that adhering to the specifications in this standard would yield high-fidelity OTC hearing aids. However, we are proposing to establish as requirements the subset of those specifications that we believe would help provide reasonable assurance of safety and effectiveness in conjunction with the other proposals in this rulemaking.

Whether to require such electroacoustic performance specifications for OTC hearing aids, and the specific values, were topics of discussion during the June 9, 2017, NASEM public workshop (Ref. 11). Additionally, public presentations of amplification measurements at FDA's hearing aid workshop showed performance differences and suitability in terms of frequency response bandwidth and smoothness across devices that presenters considered (Refs. 9, 15, 16, 22). After seeing such information, several participants opined that the Category 1 limits of ANSI/CTA-2051, together with the device latency limits (a Category 2 limit in ANSI/CTA-2051), would collectively help ensure safety and effectiveness of an OTC hearing aid with respect to its electroacoustic performance.

In addition to the performance aspects of the voluntary consensus standard, we recognize that aligning FDA regulations with a voluntary consensus standard may reduce administrative burdens while encouraging and facilitating greater availability of safe and effective OTC hearing aids. Note that we are not proposing to apply the electroacoustic performance requirements to prescription hearing aids, nor are we proposing to establish requirements for OTC hearing aids that mirror the technical data requirements under current § 801.420(c)(4). We expect that the involvement of a licensed professional for prescription hearing aids will help provide for reasonable assurance of safety and effectiveness for those devices. Similarly, although the technical data in current § 801.420(c)(4) will assist licensed professionals to select and fit a prescription hearing aid, we do not believe that the technical data are generally helpful for lay users of OTC hearing aids that meet electroacoustic performance requirements.

a. Distortion control limits. Distortion control limits describe how faithfully an OTC hearing aid reproduces a given frequency or range of frequencies at a given sound pressure level. An OTC hearing aid that produces less perceptible total harmonic distortion, plus hearing-aid-originated noise (i.e., total harmonic distortion plus noise), will deliver a higher-fidelity sound to the user, meaning that the user will be able to perceive sounds more accurately or clearly than a device with higher perceptible total harmonic distortion plus noise. Total harmonic distortion plus noise can depend on both the input and output sound pressure levels and the corresponding (level-dependent) gain settings of the device if applicable. We believe that the proposed allowable levels of total harmonic distortion plus noise, when measured as proposed at the specified sound pressure levels, will help ensure accurate or clear amplification for the user of an OTC hearing aid.

b. Self-generated noise level limit. The self-generated noise level limit describes the maximum sound pressure level of noise that the OTC hearing aid may produce, where “self-generated noise” means sounds that are present in the output but not the input. Excessive self-generated noise can obscure or overwhelm softer output sounds, preventing the user from hearing such sounds. Excessive self-generated noise may also distract or annoy users. Appropriately limiting self-generated noise will therefore help users to hear softer output sounds as well as improve their experience by avoiding the production of perceptible noise or sounds that are not input sounds. We believe that the proposed rule will appropriately limit self-generated noise.

c. Latency limit. The latency limit describes how quickly an OTC hearing aid produces the output sound relative to the input sound. A shorter latency interval means that the device takes less time to produce the output, and when short enough, the user will not perceive a delay. A perceived delay is generally most noticeable when the device amplifies the user’s own voice, causing an effect much like an echo that can be disorienting, distracting, or annoying. We believe

that the proposed latency limit will help to avoid perceptible output delays that would reduce the benefit from an OTC hearing aid.

d. Frequency response bandwidth. The frequency response bandwidth of an OTC hearing aid is the range of frequencies that the device can reproduce for the user to hear. Cutoff frequencies, both lower and upper, are the limits of the bandwidth. The device would generally not sufficiently amplify signals with frequencies outside of these limits, meaning, below the lower cutoff or above the upper cutoff. A wider bandwidth means that the device can amplify a broader range of sound frequencies for users to hear. A bandwidth that is too narrow, especially if the upper cutoff is too low, will result in insufficient amplification of critical high-frequency sounds, including but not limited to speech sounds such as /s/, /z/, /t/, and /sh/. We believe that the proposed required frequency bandwidth, 250 Hz to 5 kHz, will ensure amplification of daily speech or other environmental sounds because almost all such sounds typically fall between these proposed lower and upper cutoff frequencies.

e. Frequency response smoothness limit. The frequency response smoothness limit describes how uniformly the OTC hearing aid amplifies different frequencies over its bandwidth. A uniform frequency response when graphed would correspond to a smooth and relatively uniform curve, which is the “smoothness” described by this limit. To describe this requirement, we divide the frequency range into multiple, narrower ranges called one-third octave bands. Any given peak in a one-third octave band would have to remain below a set level compared to neighboring bands, two bands above and two bands below, based on the averages. Meeting this requirement for frequency response smoothness means that the amplification performance is consistent across frequencies for users.

If a device does not amplify sounds uniformly across frequencies, the user would potentially perceive differences in intensity for different frequencies, reducing the audio fidelity and consequently the user’s hearing perception. This may include a perceptibly altered speech quality (such as undue changes in the tone or timbre of the intended sound), which may be

distracting or annoying. In addition, device output that is relatively excessive at lower frequencies (compared to higher frequencies) poses an increased risk for damaging a user's hearing at lower frequencies. This is because the typical user has more residual hearing (i.e., better hearing thresholds) at lower frequencies, consistent with a typical sloping hearing loss, the kind of hearing loss associated with aging. We believe that the proposed frequency response smoothness limit will ensure consistent performance across frequency ranges and thereby help to provide reasonable assurance of device safety and effectiveness.

f. Performance test methods. For each of these proposed electroacoustic requirements, we are specifying performance test methods, including input and output sound pressure levels when appropriate. We are proposing specific performance test methods because different test methods could yield different results for the same metric of device performance. Thus, specifying test methods helps establish a common baseline to benchmark performance for any given device. Additionally, a common baseline would allow prospective users and others to compare electroacoustic performance across devices. Facilitating comparison shopping may also promote users' satisfaction with the OTC hearing aids that they decide to purchase.

2. Design requirements to ensure proper physical fit and prevent user injury

We are proposing that the design of an OTC hearing aid must meet certain requirements for safety and effectiveness:

- Maximum insertion depth;
- Eartip made from atraumatic materials;
- Proper physical fit; and
- Tools, tests, or software allowing the lay user to control the device and customize it to the user's hearing needs.

The above listed requirements seek to balance effective fit and safe fit of an OTC hearing aid, accomplished by users themselves, without professional assistance. An OTC hearing aid eartip (the part of the OTC hearing aid that contacts and fits into the user's ear) must fit the user so the

device performs optimally, but an OTC hearing aid must not damage the ear, including the ear canal and eardrum (tympanic membrane).

The device could damage the ear by scratching (abrading) the skin around the eartip parts, puncturing the eardrum, or exacerbating hearing loss if the device is too close to the eardrum. In particular, the skin that lines the ear canal is especially thin and delicate. The lateral (outer) third of the canal is composed of cartilage, and the medial (inner) two-thirds, which ends at the ear drum, of bone. Each of these parts of the ear is therefore quite sensitive and easily injured. To provide reasonable assurance of safety and effectiveness, the design of an OTC hearing aid must allow insertion and prolonged contact with these sensitive areas while preventing injury to them. We believe the above listed requirements would ensure proper physical fit for optimal performance while avoiding injury to the user's ear canal skin, bony inner ear canal, the eardrum, or other middle ear structures.

a. Maximum insertion depth. We considered whether we could express a design requirement for manufacturers for maximum insertion depth as a given length. However, specific anatomical dimensions such as the length of the cartilaginous and bony portions of the external auditory canal and distance to the tympanic membrane can vary greatly among adults. That is, the distance to the eardrum differs greatly from person to person. A given length may be too long for one person (potentially resulting in injury with device insertion or placement) but too short for another (potentially impairing device performance by too shallow of an insertion). In contrast, we believe that the bony-cartilaginous junction is a readily identifiable and consistent anatomical landmark that can serve as a design limit for manufacturers of OTC hearing aids. That is, we believe a practical way to describe the depth limit is to base it on the area of the ear canal corresponding to where cartilage meets bone. However, we welcome comments, particularly those with support from peer-reviewed sources, about other design requirements (e.g., in terms of absolute length) to limit the insertion depth and prevent damage to the tympanic membrane or other injuries while also promoting device effectiveness.

b. Construction from atraumatic materials. We are proposing that the eartip be encased by atraumatic materials, that is, materials that prevent injuries to the skin and bone, for example, because they are very flexible. The use of atraumatic materials reduces the chance that daily use or accidental contacts will cause damage to the delicate skin or bone of the ear.

c. Proper physical fit. We are proposing that the OTC hearing aid have features that enable users to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear. For example, the manufacturer may wish to provide interchangeable eartips of varying sizes. However, we are not proposing a specific design feature or strategy because such specificity may constrain the design of an OTC hearing aid and impede design innovations. This proposed requirement corresponds with the proposed labeling requirements to describe how users may obtain such a fit, including sizing or inserting the eartip to minimize the risk of injury.

d. Tools, tests, or software. We are proposing to codify the requirement that an OTC hearing aid must include tools, tests, or software through which a lay user can control the device and customize it to the user's hearing needs. Examples of tools, tests, or software include but are not limited to: a user-adjustable volume control, a user-adjustable tone control, the ability for a user to change preset listening programs manually, interactive software for self-selecting, testing, and fitting, or a switch to enable or disable automatically determined settings, such as acoustic environment sensing or noise cancellation. An OTC hearing aid would need to include tools, tests, or software, or some combination of those features, sufficient to customize the device to meet the user's hearing needs.

3. QS Requirements

We are soliciting further input on potential revisions to the applicable QS requirements for OTC hearing aids. The input that we have already received, while valuable, is sometimes contradictory and does not fully address FDA's concerns for the quality of medical devices. As described in section I.C, we received stakeholder input suggesting that FDA reduce the

provisions of the QS regulation applicable to the devices as the provisions are overly burdensome. We also received input that the current requirements are important and not unduly burdensome (Ref. 9). While FDA wishes to minimize regulatory burdens, we must have reasonable assurance of safety and effectiveness, which a quality system helps to provide.

In considering the range of feedback already received, we note that the QS requirements are interdependent yet inherently flexible. This scheme relies on each of the provisions working together. Further, because hearing aids are medical devices, a quality system for medical devices specifically, as opposed to a quality system for consumer electronics more generally, is necessary to provide reasonable assurance of safety and effectiveness. This is because medical device quality systems address regulatory concerns regarding safety and effectiveness that systems for consumer electronics do not.

While the use of the quality system described in part 820 would be more appropriate for OTC hearing aids and straightforward to implement than another standard with various reservations, exceptions, and modifications, FDA is open to considering alternatives to the existing QS requirements. Any such changes would be proposed in a separate rulemaking proceeding, and interested parties would have an opportunity to comment during that rulemaking. However, we welcome proposals for how the QS requirements could be modified, or an alternate approach implemented, to ensure the quality of OTC hearing aids and provide a reasonable assurance of safety and effectiveness.

Finally, with regard to the QS requirements, FDA is undertaking other separate efforts to minimize regulatory burdens for manufacturers by proposing the harmonization of part 820 with an international consensus standard.

In light of the foregoing--including contradictory input already received, the inherent flexibility of the QS requirements, the need for a quality system suited to medical devices, and other changes that FDA is proposing--we are seeking further input on potential modifications to the QS requirements that would be applicable to OTC hearing aids to inform future rulemaking.

F. Condition for Sale (Proposed § 800.30(g))

FDA is proposing to establish a condition for sale of OTC hearing aids to prevent sale to people younger than 18, helping to provide reasonable assurance of safety and effectiveness. We are proposing the condition for sale pursuant to section 709(b)(2)(D) of FDARA, which directs FDA to describe the requirements under which the sale of OTC hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online. For the purposes of this provision, we interpret “sale” broadly to include, among other transactions, leases and rentals.

The proposed condition for sale is consistent with 709(b)(2)(C) of FDARA and section 520(q)(1)(A)(ii) of the FD&C Act, which establish that OTC hearing aids are only intended for people age 18 and older. As described above, the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people. Accordingly, we are proposing to prohibit the sale of an OTC hearing aid to or for a person younger than 18 years.

FDA has considered whether other conditions for sale for OTC hearing aids are necessary in addition to the proposed labeling that includes conspicuous statements that OTC hearing aids are only intended for people age 18 and older. This proposed condition for sale provides a basis for comments on the subject.

FDA also considered whether requirements on sellers to verify the age of purchasers or, in the case of online or mail-order sales, the age of the recipient, would promote the public health. However, mindful that the current conditions for sale have been criticized as described above, we believe that a requirement to obtain proof of age could make hearing aids more difficult to obtain. For example, people with limited means or mobility may not have a government-issued photographic identification that shows their birthdate. Similarly, age verification for online or mail-order sales could impede delivery of OTC hearing aids or reduce the number of willing sellers, which could disproportionately affect OTC hearing aid access in

remote or rural areas. Moreover, FDA does not expect high demand for OTC hearing aids from or for people younger than 18. Thus, a requirement for age verification could impose a barrier to access, particularly for underserved populations, without a corresponding benefit to the public health.

FDA welcomes your comments on whether a prohibition of sales to or for people younger than 18 years, without the need to verify age, would best promote access to OTC hearing aids while protecting the hearing health of people younger than 18 years. Alternatively, we welcome your comments on what other conditions for sale may protect the hearing health of people younger than 18 years. In the case of alternative conditions for sale, FDA is particularly interested in conditions that would not disproportionately burden underserved communities. FDA is also interested in your comments on whether labeling, without the prohibition on sales, adequately protects the health of people younger than 18.

We intend to minimize burdens and provide flexibility for sellers, while also protecting the hearing health of people younger than 18, helping to promote the public health by promoting the availability of OTC hearing aids for people who are 18 and older.

G. Preemption Provisions (Proposed § 800.30(h))

FDA is proposing to codify the provisions regarding preemption and private remedies under section 709(b)(4) and (5) of FDARA to assist stakeholders in understanding the legal framework for OTC hearing aids. These provisions are not codified in the FD&C Act, meaning they do not appear under Title 21 of the U.S. Code, but apply nonetheless. We believe that including these provisions in the Code of Federal Regulations will assist our stakeholders, who may not be as familiar with requirements that are not codified in the FD&C Act, such as these, by consolidating applicable requirements in one location that is more familiar.

This may be particularly helpful because FDARA added to the existing preemption framework for devices. In general, under section 521(a) of the FD&C Act, device requirements established by a State (or a political subdivision) are preempted when the requirements are

different from, or in addition to, requirements applicable to the device under the FD&C Act and which relate to the safety or effectiveness of the device or to any other matter included in the requirements applicable to the device. FDA may by regulation grant or deny exemptions to this preemption in response to an application from a State (or political subdivision) under certain conditions specified in section 521(b) of the FD&C Act. Prior to the enactment of FDARA, FDA issued regulations in response to such applications, most of them relating to hearing aids, which are codified in part 808.

However, section 709(b)(4) of FDARA established preemption specific to OTC hearing aids that is different from the general rule for preemption under section 521(a) of the FD&C Act. Although FDARA did not explicitly address the existing exemptions from preemption related to hearing aids, section 709(b)(4) of FDARA applies preemption to any requirement of a State (or local government) specifically related to hearing products, that would restrict or interfere with commercial activity involving OTC hearing aids (which, as mentioned above, we will use as shorthand in this document for the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online), that is different from, in addition to, or otherwise not identical to, FDA's regulations issued under FDARA section 709(b). We are therefore proposing to amend the scope of part 808 to reflect the additional preemption set by FDARA (see section III.I.1).

1. FDARA Preempts State Regulation of OTC Hearing Aids

Under FDARA section 709(b)(4), the OTC Hearing Aid Controls that are the subject of this rulemaking, proposed § 800.30, if finalized, would preempt any State or local requirement specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids, that is different from, in addition to, or otherwise not identical to, the OTC Hearing Aid Controls, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

FDA interprets section 709(b)(4) of FDARA, including the terms therein, as consistent with its purpose that State or local government requirements specifically related to hearing products not restrict or interfere with commercial activity involving OTC hearing aids. For example, we interpret this provision as preempting State or local requirements specifically related to hearing products that would restrict or interfere with leases, consignments, or deliveries of OTC hearing aids, though not explicitly mentioned in FDARA, because such activities fall within the commercial activity involving OTC hearing aids covered by the provision, in this example, within the marketing, sale, dispensing, use, and/or distribution. Further, the FDARA preemption provision applies to requirements specifically related to hearing products generally, as opposed to devices or hearing aids more specifically, where such requirements restrict or interfere with commercial activity involving OTC hearing aids.

As explained, we do not interpret section 709(b) of FDARA as necessarily preempting State requirements regulating professional services such as speech pathology, audiology, or fitting. A State could, for example, continue to regulate such professional services generally. However, to the extent State or local governments require that purchasers of OTC hearing aids seek those services, such requirements would be preempted by section 709(b)(4) of FDARA as interfering with or restricting commercial activity involving OTC hearing aids. The same would be true were a State, for example, to require providers to undertake an activity, such as certification and examination specific to hearing aids, in order to sell OTC hearing aids.

2. Generally Applicable State and Local Requirements Are Not Necessarily Preempted Under FDARA

As noted in section III.B, FDA does not interpret FDARA to preempt generally applicable requirements. By “generally applicable,” we mean that the requirement relates to other products in addition to hearing products, to services not specific to hearing products, or to

unfair trade practices in which the requirements are not limited to hearing products.¹¹

Requirements that apply to any place of business that offers goods or services for sale would likely be generally applicable and therefore not preempted (see also § 808.1(d)(1)). Similarly, requirements that apply to certain places of business may be generally applicable provided the requirements do not attach on account of selling, or other commercial activity involving, hearing products. State or local requirements that make compliance with Federal regulations enforceable by State or local authorities would also not generally be preempted. The examples below focus only on the FDARA preemption provision that applies to OTC hearing aids.

a. Example 1. For example, any given pharmacy may be subject to certain State licensing requirements that apply regardless of whether the pharmacy sells OTC hearing aids; it would not be exempt from such licensing requirements merely because it sells OTC hearing aids. Similarly, a requirement to include terms of sale or return on the receipt that applied also to the sales of other (non-hearing) products would not be preempted.

b. Example 2. In contrast, requirements that attach on account of the sale of hearing products (or would not attach but for the sale of hearing products), would not be “generally applicable.” For example, a requirement that any place of business must obtain a license or certification to sell OTC hearing aids would be a requirement specifically related to hearing products. In addition, it would serve to restrict or interfere with commercial activity involving OTC hearing aids and would be different from, in addition to, or not otherwise identical to, the regulations issued under section 709(b) of FDARA. Therefore, it would be preempted.

A requirement may attach on account of the sale of hearing products in a more indirect manner as well, and if it was in effect different from, in addition to, or not otherwise identical to the terms of the statute or Federal regulations, and if it restricted or interfered with commercial

¹¹ We refer to hearing products more generally, not just OTC hearing aids. We wish to make clear that a State or locality may not establish requirements for hearing products if those requirements would restrict or interfere with commercial activity involving OTC hearing aids. However, we do not interpret section 709 of FDARA as preempting requirements that apply only to prescription hearing aids (provided they do not restrict or interfere with commercial activity involving OTC hearing aids) but such requirements could be preempted under section 521 of the FD&C Act.

activity involving OTC hearing aids, it would be preempted. That is, a State or local requirement may appear on its face to be generally applicable, but if in practice it was specifically related to hearing products and would restrict or interfere with commercial activity involving OTC hearing aids, the State or local requirement would be preempted.

c. Example 3. A requirement that a retailer may only sell OTC hearing aids when it has an audiologist on premises would require the involvement of a licensed person in at least some cases. This requirement would restrict or interfere with commercial activity involving OTC hearing aids, including by requiring the involvement of a licensed person, and would be preempted.

d. Example 4. Similarly, a requirement that sellers advise purchasers of any hearing aids, whether prescription or OTC, of specific medical information not required in the OTC Hearing Aid Controls would be preempted with respect to the sale of OTC hearing aids. Although the requirement attaches on account of the sale of hearing aids more generally (not just OTC devices), it is “specifically related to hearing products” and would operate as a condition of sale that is different from, in addition to, or otherwise not identical to those proposed in this rulemaking. The requirement would also restrict or interfere with commercial activity involving OTC hearing aids. Therefore, the requirement would be preempted as applied to the sale of OTC hearing aids.

e. Example 5. A professional or ethical requirement that deemed a sale to be professional malpractice if the dispenser permitted the sale of any hearing aid without consultation would be preempted under FDARA. It specifically relates to hearing products and by requiring consultation prior to the sale of an OTC hearing aid, it would restrict or interfere with commercial activity involving OTC hearing aids even though the requirement on its face applies only to the dispenser (who must meet licensing requirements).

f. Example 6. A requirement that a seller maintain a statement of medical examination, in connection with the sale of a hearing product, would be preempted under FDARA because such

a condition of sale would restrict or interfere with commercial activity involving an OTC hearing aid. Moreover, the requirement for a statement of medical evaluation would restrict or interfere with commercial activity involving OTC hearing aids by requiring the involvement of a licensed person during the course of the commercial activity.

3. Requirements for Professionals and Establishments

As with generally applicable requirements, we do not interpret section 709 of FDARA as generally prohibiting the regulation of professionals or establishments or exempting them from applicable professional requirements, even in the case that the professional or establishment only undertakes activities related to OTC hearing aids. Thus, a person that purports to be a specially licensed professional or establishment would be subject to applicable State and local requirements. Such requirements may include periodic professional examination or mandating the availability of testing equipment.

FDA does, however, interpret section 709 of FDARA as preempting certain kinds of professional or establishment requirements. To use one specific example, many States have established definitions for hearing aid fitters, dispensers, or other sellers and servicers. In some cases, State or local requirements may deem an individual or establishment to be a dispenser (or other defined term) by virtue of engaging in the sale of or providing services for hearing aids. That status in turn incurs legal obligations. As explained, we interpret section 709 of FDARA as preempting such requirements to the extent that they would require the involvement of a licensed person for consumers to access OTC hearing aids or would otherwise restrict or interfere with commercial activity involving (the servicing, marketing, sale, dispensing, use, customer support, or distribution of) OTC hearing aids.

For the reasons explained in section III.B regarding the definition of “licensed person,” we are specifying certain related terms that would not on their own, as they relate to OTC hearing aids, indicate professional or specialized obligations. For example, under the proposed definition of “licensed person,” identifying as a hearing aid “dispenser” would not imply

licensure. Note that we would consider a person identifying as a “licensed dispenser” to be subject to State or local requirements applicable to licensed dispensers and therefore considered a “licensed person” under section 709(b)(4) of FDARA.

The examples below focus only on the FDARA preemption provision that applies to OTC hearing aids.

a. Example 7. In contrast to identifying as a dispenser (without using the word “licensed”), as proposed, identifying as an audiologist or hearing aid fitter, for example, may imply licensure, depending on State and local requirements. Thus, a person who advertises as an audiologist or hearing aid fitter--professional services that may be provided, but cannot be required to be provided, to sell OTC hearing aids--would be subject to State requirements that apply to audiologists or hearing aid fitters. This would be true even if such an audiologist or fitter only sold OTC hearing aids.

b. Example 8. In contrast, a person who advertises as a hearing aid dispenser or seller, and who only sells OTC hearing aids, cannot be required to obtain specialized licenses to engage in commercial activity involving OTC hearing aids.

c. Example 9. As in Example 7, a person who only sells OTC hearing aids but advertises as a licensed dispenser even though such licensing is not required to sell OTC hearing aids--the person purports to be a licensed person, not a “dispenser” more generally--would be subject to State or local requirements that apply to licensed dispensers.

We are proposing a preemption provision that speaks specifically to professional requirements in order to clarify in the regulations that the servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, on its own, does not obligate a person to obtain specialized licenses, certificates, or any other State or local sanction.

H. Proposed Repeal of Conditions for Sale and Modifications for Prescription Labeling

(§§ 801.420, 801.421, 801.422)

FDA is proposing to repeal the conditions for sale for hearing aids, § 801.421, because these would no longer be necessary. Currently, those conditions apply to all hearing aids, but section 520(q)(2) of the FD&C Act specifies that OTC hearing aids will be exempt from §§ 801.420 and 801.421 or any successor regulations. Instead of continuing to apply those conditions to non-OTC hearing aids, FDA is proposing to repeal them. Additionally, FDA is proposing to remove the current labeling requirements for hearing aids in § 801.420 and issue prescription labeling requirements under § 801.422, which would be in addition to the prescription labeling requirements in § 801.109.

The repeal of § 801.421 and the amendments to the labeling requirements (amending the current labeling requirements, moving them to a new section, and removing § 801.420) would have further regulatory implications. In proposing new § 801.422, FDA is not relying on its restricted device authority in section 520(e) of the FD&C Act. Therefore, if this proposed rule is finalized, class I and class II hearing aids would no longer be “restricted devices” under section 520(e) of the FD&C Act. As such, certain Federal requirements related to restricted devices would no longer apply to class I and class II hearing aids. Further, the basis for some of FDA’s exemption decisions about preempted State requirements would change. The next section of this document discusses those changes along with the additional Federal preemption implications of FDARA and how we would remove, update, or clarify those regulations. Repeal of the conditions for sale would also obviate the need for the guidance entitled “Conditions for Sale for Air-Conduction Hearing Aids”; if the repeal of the conditions for sale is finalized, we would withdraw that guidance (Ref. 8).

1. Repeal of Conditions for Sale § 801.421

As summarized in section I.C.2, the conditions for sale of hearing aids under § 801.421 require a statement of medical evaluation, unless waived by a user 18 years of age or older; the availability of a user instructional brochure and an opportunity to review it; and records of the

statements of medical evaluation or waiver. The conditions also provide an exemption from the requirements in § 801.421 for auditory trainers.

In light of the fact that FDA is proposing to clarify that non-OTC hearing aids would be prescription devices, such hearing aids would be subject to State and local requirements for obtaining written or oral authorization of a practitioner licensed by State law to administer the use of the devices. For example, some States license audiologists to administer the use of prescription hearing aids for an adult, so adults could obtain a prescription for hearing aids from an audiologist in those States. In the case of people younger than age 18, the proposed prescription labeling statements described in the next section of this document would in manner and form emphasize the importance of medical evaluations. Because prescription hearing aids will require a written or oral authorization from a practitioner licensed by law to administer the device, and because we are proposing certain labeling requirements in a certain manner and form, FDA is proposing to repeal the conditions for sale (including the requirement for a medical evaluation and for providing a user instructional brochure) because they would no longer be necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. Thus, hearing aids that do not meet the definition of, or the requirements for, OTC hearing aids would all be prescription hearing aids, but they would no longer be restricted devices. We expect that the application of prescription requirements with the removal of device restrictions will not increase the burden to obtain non-OTC hearing aids, and that the change will promote consistency with other products, easing the burden on purchasers. Specifically, hearing aids will be either prescription or OTC; users and other interested people would not also need to inquire whether a device is restricted.

Additionally, repeal of the requirements discussed above would obviate the need for the exemption for group auditory trainers, which we are correspondingly proposing to repeal.

2. Revised Labeling for Prescription Hearing Aids

We continue to believe that the labeling requirements are necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. As such, we are proposing to retain most of the required information currently in § 801.420 in substance, except as revised below, and place the proposed revised labeling requirements that would be specific to prescription hearing aids in § 801.422, thereby removing § 801.420. These proposed revisions are to ensure that the wording is consistent with and similar to the proposed labeling statements for OTC hearing aids when appropriate. In particular, we are proposing to revise the labeling statements to be more understandable and, when addressed to users and prospective users, less technical.

In general, as summarized in section II, a device's labeling must bear adequate directions for use and certain adequate warnings in the manner and form necessary to protect the user (see section 502(f) of the FD&C Act). We have defined "adequate directions for use," in part, as directions by which a layperson can use the device safely and for the purposes for which it is intended (see § 801.5). However, we have exempted prescription devices from the requirement for labeling to bear adequate directions for use provided they meet certain conditions (see § 801.109). For prescription devices, labeling must bear, among other statements, information for use under which practitioners licensed by law to administer the device can use it safely and for the purpose for which it is intended (see § 801.109(c)). In any case, the labeling for a device must not be false or misleading in any particular (see section 502(a)(1) of the FD&C Act). Labeling may be false or misleading because, among other reasons, it fails to reveal facts material to its use (see section 201(n) of the FD&C Act). Therefore, prescription hearing aid labeling must include certain adequate warnings as well as information for the licensed professional to use the device safely and for the purpose for which it is intended, and the labeling must not fail to reveal certain material facts.

To determine whether those requirements are met, we consider the sale, distribution, and use of prescription hearing aids. In the case of prescription hearing aids, a prospective user

would obtain one from a practitioner licensed by law in that State. However, the professional qualifications for fitters and other licensed practitioners, as well as dispensers more generally, vary widely. Therefore, we are proposing to require information for dispensers to ensure necessary warnings are conveyed in an adequate manner and form for every device. The proposal includes warnings: (1) of possibilities for underlying pathological conditions, (2) against use in people younger than 18 without a medical evaluation, and (3) of injury potential from high output.

We are further proposing to require the disclosure of certain technical specifications, which is necessary to provide fitters and dispensers information for the safe and effective use of the device. This information is material to the use of the device, as this information would be necessary for a hearing health professional to select an appropriate device. Without this information, a hearing health professional would be unable to determine a safe and effective device for the user without unnecessarily increasing the risks to health to the user. This provision includes a proposed requirement that measurement of the specifications conforms to ANSI/ASA S3.22-2014, “Specification of Hearing Aid Characteristics,” to provide for uniformity in testing and measurement, which in turn aids hearing health professionals in selecting or fitting an appropriate prescription hearing aid.

The proposed user labeling requirements are also intended to provide adequate warnings against use in certain pathological (“red flag”) conditions, and by children, where the use would be dangerous to health; as well as adequate warnings against unsafe dosage or methods or duration of administration or application. We propose that this manner and form are necessary for the protection of the users.

Once a user obtains a prescription hearing aid, use of the device occurs without direct supervision of a licensed professional, and notably, such use is generally intended to occur over long periods each day, every day. Therefore, in addition to the proposed information for hearing health professionals summarized above, we are proposing warnings and information specifically

for users. We intend this information to be more understandable for laypeople while communicating warnings against use in certain pathological (“red flag”) conditions, against use in children without a medical evaluation, and in a manner and form that are necessary for the protection of the users.

For the reasons explained above, we believe that the proposed labeling requirements for prescription hearing aids are necessary to provide reasonable assurance of safety and effectiveness. This proposal also maximizes consistency with OTC hearing aid labeling to reduce the burden on manufacturers that wish to offer both categories of hearing aids. Although we are proposing the foregoing warnings and information in manner and form as are necessary for the protection of users, the specificity of this proposal would also encourage uniformity while conveying essential information appropriate for the type of hearing healthcare delivery. By minimizing burdens and fostering familiarity, the specificity and consistency would also help promote availability and use of prescription devices.

To provide for clarity and efficient enforcement of the FD&C Act, FDA is proposing to provide explicitly that a prescription hearing aid that does not satisfy the labeling requirements of proposed § 801.422, if finalized, would be misbranded under sections 201(n), 502(a), and 502(f) of the FD&C Act. Moreover, as explained, we believe that the labeling statements as we propose to revise them are material to and necessary for the safe and effective use of prescription hearing aids. Thus, we believe that an explicit misbranding provision in the prescription labeling requirements will provide for clarity as well as the efficient enforcement of the FD&C Act.

If we finalize the repeal of the conditions for sale under § 801.421, we would correspondingly withdraw the guidance document entitled “Conditions for Sale for Air-Conduction Hearing Aids” because that guidance announces our policy regarding certain provisions of § 801.421 and would cease to be relevant (Ref. 8).

I. Proposed Amendments to Previous Exemption Decisions (Part 808)

A State or a political subdivision (e.g., a city) may not establish or continue in effect its own requirement with respect to a device for human use if that requirement is different from, or in addition to, a requirement applicable under the FD&C Act to the device (see section 521(a) of the FD&C Act). Under section 521(b) of the FD&C Act, upon application of a State or political subdivision of a State, FDA may, by regulation, exempt from preemption a State or political subdivision requirement applicable to a device if: (1) the requirement is more stringent than a requirement under the FD&C Act that would be applicable to the device if an exemption were not in effect or (2) the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of the FD&C Act. FDA has granted some exemption requests and most, if not all, of FDA's decisions to grant exemption from preemption were based on the State or local requirement being more stringent.

FDA's decisions on States' applications for exemption from Federal preemption under section 521 of the FD&C Act are codified in regulations under part 808, subpart C. The regulations codifying these decisions include both granting and denial of exemption from preemption. Therefore, "exemption decisions" as used in this document include both types of decisions. Most of the applications for exemption from Federal preemption related to State medical device requirements that apply to hearing aids, as they existed at the time of the exemption decisions, and that were different from or in addition to the requirements in §§ 801.420 and/or 801.421. Because FDARA directs FDA to establish different requirements for some hearing aids that are not subject to section 521(b) of the FD&C Act, many of the current exemption decisions would not accurately reflect the regulatory framework for hearing aids under FDARA and the FD&C Act as amended. Moreover, if we finalize the changes we are proposing to the existing requirements for hearing aids in §§ 801.420 and 801.421, the previous exemption decisions based on those requirements may no longer apply.

1. Exemption Decisions Under Section 521(b) Are Affected by FDARA (Proposed § 808.1(g))

As explained in section III.G of this document, and as indicated above, some decisions on exemption from Federal preemption under section 521(b) of the FD&C Act would no longer accurately reflect the applicability of State requirements after the enactment of FDARA and upon establishing the OTC category of hearing aids. To assist stakeholders to understand the changes effected by FDARA, we are proposing to codify how FDARA limits the scope of exemption decisions under section 521(b) of the FD&C Act. We believe this proposal will provide a concise reference for stakeholders to ascertain the changes effected by FDARA.

Note that we are not considering exemptions from section 709(b)(4) of FDARA for State or local requirements. This is because FDARA does not provide a parallel mechanism to exempt State or local requirements regarding hearing products that would restrict or interfere with commercial activity involving OTC hearing aids. We refer to preemption under section 709(b)(4) simply to clarify how FDARA affects State and local requirements.

2. Removal of Regulations Codifying Exemption Decisions Affected by Amendments to § 801.420 and Repeal of § 801.421 if Finalized

As explained above, FDA's exemption decisions are codified in regulations under part 808, subpart C. These decisions were issued in the 1980s and apply to the specific State provisions identified in the regulations and the specific Federal requirements in effect at the time. As mentioned above, most of the exemption decisions related to State medical device requirements that apply to hearing aids and that were different from or in addition to the requirements in §§ 801.420 and/or 801.421. We are proposing to remove all of the regulations in part 808 related to hearing aids; that is, almost all regulations codifying the previous decisions in §§ 808.53 through 808.101, except for the portions of § 808.55 (California) that do not relate solely to hearing aids. We are proposing this because the exemption decisions codified in those regulations may no longer apply due to changes to the Federal hearing aid requirements as proposed in this rulemaking and changes to the specific State provisions we have identified in those regulations since the decisions were made over 30 years ago.

In particular, the repeal of the conditions for sale would eliminate specific Federal requirements that preempt certain State or local requirements. As such, whether we previously granted or denied exemptions, the exemption decisions would no longer apply because the State or local requirements that differed from, or were in addition to, § 801.421 would no longer be preempted. Therefore, we are proposing to remove the State-specific regulations in part 808 codifying exemption decisions pertaining to the conditions for sale for hearing aids because those decisions would no longer be applicable if the conditions for sale are repealed.

Also, the proposed amendments to the hearing aid labeling requirements may affect the exemption decisions relating to § 801.420. Although the proposed § 801.422 is similar to § 801.420 in that it too would address labeling for hearing aids, the labeling requirements are not identical to those in § 801.420 and include substantive changes. Moreover, FDA is aware that several States have modified their requirements that were the subject of the exemption decisions since they applied for exemptions, in which case the exemption decision may no longer be applicable. Thus, not only will the Federal requirements change, but the State requirements that were the subject of the exemption decisions may have changed too since the decisions were made.

Given that the exemption decisions were based on specific Federal requirements and specific State requirements that existed at the time of the decision, changes in either may affect those decisions such that they are no longer applicable. Because the exemption decisions relating to hearing aid labeling requirements may no longer be applicable, we are proposing to remove the regulations codifying these decisions. We specifically seek comments from the States regarding the proposed removal of the regulations in part 808, subpart C, codifying these exemption decisions. For example, if a State disagrees with the proposed removal of the regulation(s) in part 808, subpart C, because the State believes the exemption decision still applies, a statement and explanation why in the comments may be helpful.

We note that when § 801.422 is finalized and in effect, no State or political subdivision of a State may establish or continue in effect with respect to prescription hearing aids, any requirement which is different from, or in addition to, any requirement in § 801.422 (see section 521(a) of the FD&C Act). However, a State or political subdivision thereof may apply for an exemption from preemption by following the process in part 808 for any requirement that is preempted by § 801.422 (see also section 521(b) of the FD&C Act).

J. Other Proposed Amendments

FDA is proposing several amendments to provide for consistency, including with the proposals in this rulemaking, if finalized, and to improve clarity. We are proposing the following:

- To realign the hearing aid classification regulations by sound conduction mode so that legacy air-conduction hearing aids, wireless air-conduction hearing aids, and self-fitting air-conduction hearing aids would be under one classification regulation; bone-conduction hearing aids would be under a separate classification regulation.
- To clarify that air-conduction hearing aids are subject to § 800.30 or § 801.422, as applicable, and bone-conduction hearing aids are subject to § 801.422.
- To revise the special control currently in § 874.3305(b)(1) for consistency with the special control currently in § 874.3325(b)(3). Although the proposed revision to § 874.3305(b)(1) would require demonstration of electrical safety and thermal safety, we believe that generally manufacturers of wireless air-conduction hearing aids regulated under § 874.3305 have been evaluating these safety aspects for their devices and therefore, this proposed revision would have little to no impact on these manufacturers.
- To revise the special controls for wireless hearing aids currently in § 874.3305(b) and for self-fitting hearing aids currently in § 874.3325(b) to eliminate redundancy, for example, removing special controls that would be addressed by the proposed labeling requirements for both OTC and prescription hearing aids.

- To revise §§ 874.3315 and 874.3950 to clarify that these devices are subject to the prescription hearing aid labeling requirements, including in proposed § 801.422.
- To clarify that a tympanic membrane contact hearing aid under § 874.3315 is a wearable device for purposes of prescription hearing aid labeling.

We are also proposing non-substantive modifications to the decisions regarding exemption from Federal preemption in part 808 to assist stakeholders to understand the subject matter of the individual exemption decisions.

1. Realignment of Hearing Aid Classification Regulations by Sound Conduction Mode

To increase clarity and to reduce administrative burdens associated with interpreting regulations, we are proposing to separate the classification regulations for bone-conduction and air-conduction hearing aids. We believe this will increase clarity because air-conduction devices are technologically more similar to each other than they are to bone-conduction devices. In addition, section 520(q)(1)(A)(i) defines an OTC hearing aid as a device that, among other criteria, uses the same fundamental scientific technology as air-conduction hearing aids that are wearable devices. Therefore, bone-conduction hearing aids do not fall within the scope of the OTC hearing aid definition and moving them to a separate classification regulation (proposed § 874.3301) will help make that clear. Tympanic membrane contact hearing aids also do not fall within the scope of the OTC hearing aid definition because, among other reasons, they do not use the same fundamental scientific technology as air-conduction hearing aids, and as specified in § 874.3315, they will continue to be regulated as prescription devices.

The proposed realignment of the air-conduction hearing aid types would also locate all OTC hearing aids within the same classification regulation; however, not all air-conduction hearing aids would be OTC hearing aids. For example, high-output air-conduction devices would be prescription. Further, transcutaneous air conduction hearing aid systems entail surgical implantation of a tube to conduct sound, so we do not consider them suitable for OTC availability; the devices will continue to be regulated under § 874.3950. The realignment will not

affect any device that does not use the same fundamental scientific technology, such as cochlear implants (product code MCM) or implantable middle ear hearing devices (product code MPV).

In realigning the regulations by sound conduction mode, we are not proposing to reclassify any device or change the exemption status under section 510(m)(2) of the FD&C Act for premarket notification for any device type (see 21 U.S.C. 360(m)(2)). For example, wireless air-conduction hearing aids regulated under § 874.3305 would continue to be class II exempt, subject to the limitations of exemption in § 874.9, and special controls would continue to apply to these devices in addition to the general controls. (The proposed general controls under § 800.30 or § 801.422, if finalized, would also apply.) As of the effective date of the final rule, we would realign current product codes to correspond with the revised regulation numbers for consistency but would not otherwise change the codes. Also, we would change the name of each classification regulation to reflect the sound conduction mode.

Note that the regulation for air-conduction hearing aids would embody a split classification, where different devices under the regulation would have different classifications and special controls depending on the technology and design. As discussed above, we would also amend the wireless hearing aid special controls to provide for consistency with the special controls for self-fitting hearing aids, and we would amend the special controls for wireless hearing aids and self-fitting hearing aids to eliminate redundancy.

2. Non-Substantive Revisions to Exemption Decisions for Clarity and Ease of Use

In addition to the amendments in part 808 explained in section III.I., we are proposing to amend the remaining State-specific regulation in part 808 to include paragraph headings that would appear in italics. Currently, the regulations do not include paragraph headings and, as such, require stakeholders to look elsewhere to understand the content of the State or local requirements as they were at the time FDA made an exemption decision. The paragraph headings will assist stakeholders by briefly describing the subject of the individual exemption decisions, thereby providing additional information and context for stakeholders.

IV. Findings Regarding Premarket Notification

FDA may, in appropriate circumstances, exempt a class II device from premarket notification requirements under section 510(m)(2) of the FD&C Act. Section 709(b)(3) of FDARA directs FDA to make such findings, that is, to determine whether OTC hearing aids require a report under section 510(k) to provide reasonable assurance of safety and effectiveness. As described in section I.B, legacy and wireless air-conduction hearing aids are exempt from section 510(k) subject to the limitations of exemption, and we are not proposing to alter the exemption status of such devices.

Self-fitting air-conduction hearing aids are not currently exempt. FDA classified this device type in October 2019 (see 84 FR 57610), and the Agency does not have sufficient information or experience with this device type to exempt these devices from premarket notification. Accordingly, FDA has determined that, at this time, reports under section 510(k) continue to be necessary to provide reasonable assurance of safety and effectiveness. We therefore do not propose to exempt them at this time.

V. Proposed Effective and Compliance Dates

A. Effective Date

FDA proposes that this rule, if finalized, be effective 60 days after the publication of the final rule in the *Federal Register*. We propose the following compliance dates:

B. Compliance Date for Hearing Aids Not Legally Offered for Sale Prior to the Effective Date

For hearing aids that have not been offered for sale prior to the effective date of the final rule, or have been offered for sale but are required to submit a new 510(k) under 21 CFR 807.81(a)(3), compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after the effective date of the final rule. If a person (e.g., manufacturer) markets such a device without complying with the new or revised requirements or if applicable, receiving 510(k)

clearance, then FDA would consider taking action against such person under our usual enforcement policies.

C. Compliance Date for Hearing Aids Legally Offered for Sale Prior to the Effective Date

For hearing aids that have been legally offered for sale prior to the effective date of the final rule, including those that already have a 510(k) clearance, compliance with the new or revised requirements that apply to the hearing aid must be achieved 180 days after the effective date of the final rule (i.e., 240 days after the publication of the final rule). After that date, if a person (e.g., manufacturer) continues to market such a device but does not comply with the new or revised requirements that apply to the device, then FDA would consider taking action against such person under our usual enforcement policies.

At present, legacy and wireless air-conduction hearing aids are exempt from section 510(k) of the FD&C Act, subject to the limitations of exemption described in § 874.9. (Legacy hearing aids are class I devices and are 510(k) exempt under section 510(l)(1) of the FD&C Act.) However, self-fitting air-conduction hearing aids are not exempt and, therefore, are subject to premarket notification requirements. We believe that modifications to hearing aids, including labeling changes, to comply with the proposed OTC Hearing Aid Controls may exceed the limitations of exemption, for example because the device was formerly intended for use by healthcare professionals only. We believe that labeling changes for such hearing aids to comply with the proposed prescription hearing aid labeling requirements are less likely to exceed the limitations of exemption.

VI. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential

economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Based on our preliminary analysis, OMB's Office of Information and Regulatory Affairs has determined that this proposed rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We believe we can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. The estimated annualized cost over 10 years is \$0.009 million per firm, which is unlikely to represent more than 3 percent to 5 percent of the revenue of an affected manufacturer. However, we note that some uncertainty exists as to these impacts, so we have chosen to draft an initial regulatory flexibility analysis. We request comments relating to the effect of this proposed rule on small manufacturers.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would define a new regulatory category for OTC hearing aids and make corresponding changes to the existing regulatory framework, including defining hearing aids not meeting the proposed OTC requirements as prescription medical devices, as well as providing new labeling requirements for both OTC and prescription hearing aids. This proposed rule, if finalized, would generate potential cost savings for consumers with perceived mild to moderate hearing loss who wish to buy lower cost hearing aids not bundled with

professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. The proposed rule, if finalized, would also generate costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. Table 3 summarizes our estimate of the annualized costs and the annualized benefits of the proposed rule, if finalized.

Table 3.-- Summary of Benefits, Costs and Distributional Effects of Proposed Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$63	\$6	\$147	2020	7%	10 years	
		\$63	\$6	\$147	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential increase in hearing aid and hearing technology use, leading to associated health benefits, potential fostering of innovation in hearing aid technology.						
Costs	Annualized Monetized \$millions/year	\$1-	\$1	\$2-	2020	7%	10 years	
		\$1-	\$1	\$2-	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Potential loss of consumer utility from inability to buy existing hearing aids under existing conditions						
Transfers	Federal Annualized Monetized \$millions/year					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized Monetized \$millions/year					7%		
						3%		
From/To	From:			To:				
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in

the docket for this proposed rule (Ref. 23) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental impact of this proposed rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of increased use and eventual disposal of OTC hearing aids that will need to be handled if the proposed rule is finalized.

The environmental assessment (EA) considers environmental impacts related to additional waste to landfills at municipal solid waste (MSW) facilities. The proposed action would increase the availability and use of hearing aid devices, which would result in additional waste from increased disposal of these devices and their associated batteries and an increase in industrial waste associated with any domestic production to meet market demand for the new devices. Overall, given the current limited use of these devices, projected slow growth with increase in availability, and the small mass of waste material to be disposed or recycled, the proposed action is not expected to have a significant impact on MSW, landfill facilities, and the environment.

The Agency has concluded that the proposed rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact (FONSI) and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, are on display with the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA invites comments and submission of data concerning the EA and FONSI.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501-3521). A description of these provisions is given in the

Description section of this document with an estimate of the annual recordkeeping and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Device Labeling Regulations; OMB Control Number 0910-0485--Revision

Description: FDA is proposing to establish a regulatory category and related rules for OTC hearing aids to improve access to hearing aid technology for Americans. FDARA amended the FD&C Act by placing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls, which is what these rules would be.

Alongside the OTC category, we are proposing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the eventual OTC category while continuing to provide a reasonable assurance of safety and effectiveness. We believe the proposals set forth in this rulemaking will promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology. The set of general controls we are proposing, Over-the-Counter Hearing Aid Controls, would apply to all hearing aids that meet the definition of an OTC hearing aid under the FD&C Act, regardless of the device's class. Among other provisions, the controls would include requirements for labeling and device design, as well as a condition for sale to prevent the sale and use of the devices by people younger than

age 18. We are also proposing to remove the labeling requirements in the existing restrictions but establish a new regulation for labeling specific to prescription hearing aids. The new prescription labeling requirements would be similar to the current labeling requirements but maintain consistency with the new labeling requirements for OTC hearing aids (for example, so that “red flag” conditions, as revised, will be the same). We are proposing to repeal the other existing restrictions, i.e., the conditions of sale, because, if this rule is finalized as proposed, the new labeling requirements for prescription hearing aids, the requirement for a prescription, and other existing requirements would provide reasonable assurance of safety and effectiveness.

Description of Respondents: Respondents to the information collection are manufacturers of hearing aids.

We estimate the burden of the collection of information as follows:

Table 4.--Estimated One-Time Burden^{1,2}

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours	Total Capital Costs
Understanding and implementing new regulatory requirements from hearing aids rule	105	1	105	284	29,820	\$4,100,000
Hearing aids relabeling; one-time burden	105	8	840	68	57,120	\$6,000,000

¹ There are no operating and maintenance costs associated with this collection of information.

² Numbers have been rounded to the nearest whole number.

Table 5.--Estimated Annual Recordkeeping Burden^{1,2}

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Proposed labeling disclosures under 800.30(c)(2) and 801.422(c)(2); Hearing aids; electronic version of user instructional brochure	105	8	840	1	840

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded to the nearest whole number.

Table 6.--Estimated Annual Third-Party Disclosure Burden^{1,2}

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
OTC Hearing Aid Controls--800.30	105	7	735	19	13,965
Prescription Hearing Aid Labeling--801.422	105	1	105	19	1,995

Total	15,960
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¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers have been rounded to the nearest whole number.

Our burden estimate is based on FDA Uniform Registration and Listing System data; FDA's Operational and Administrative System for Import Support data; informal communications with industry; and our knowledge of and experience with information collection pertaining to medical device labeling. We intend the burden estimates to be consistent with our Preliminary Regulatory Impact Analysis (PRIA) for this rulemaking (Ref. 23).

Estimated One-Time Burden: OTC Hearing Aids proposed rule--one-time burden (Recordkeeping): As noted in the PRIA for this proposed rule, we estimate it will take 3 hours each for an executive, a lawyer, and a marketing manager to read and understand the rule. Also included in our estimate is time for revising guidelines or standard operating procedures. We assume this may take up to 25 hours for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer. Therefore, we estimate a one-time recordkeeping burden of 284 hours for each manufacturer.

OTC Hearing Aids proposed rule--one-time relabeling burden (Third-Party Disclosure):

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840). The labeling cost model used in the PRIA suggests, based on a compliance period of 6 months, a one-time estimated third-party disclosure burden for relabeling of about 68 hours per product.

We request comments on these estimates.

Estimated Annual Burden: Over-the-Counter Hearing Aid Controls--§ 800.30 (Recordkeeping and Third-Party Disclosure): Proposed § 800.30 sets forth labeling requirements for OTC hearing aids. Proposed § 800.30(c)(1) describes the warnings and other important information that the outside package must bear. Additionally, manufacturers must include on the outside package label a weblink to all labeling and any additional resources, their return policy or lack thereof, and, if the OTC hearing aid is used or rebuilt, they must declare that fact.

Proposed § 800.30(c)(2) describes device-specific requirements for labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; other specified information; and any other information necessary for adequate directions for use as defined in § 801.5. Also required under proposed § 800.30(c)(2) is the identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician; the technical specifications required by § 800.30(c)(4); a description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid; if applicable, information regarding repair service; and, if applicable, a summary of all clinical or non-clinical studies conducted to support the performance of the OTC hearing aid.

Proposed § 800.30(c)(3) provides requirements for the labeling on an OTC hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture and if applicable, information regarding the battery. Also, if the OTC hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

We include no estimate for provisions under proposed § 800.30(c)(1)(i)(A) through (D), (c)(2)(i)(A) and (B), and (c)(2)(iii)(A) through (D) because we consider the labeling to be “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public,” consistent with 5 CFR 1320.3(c)(2). Thus, those labeling provisions are not within the definition of collection of information.

The PRIA for this proposed rule estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under proposed §§ 800.30(c)(2) and 801.422(c)(2)).

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

We request comments on these estimates and assumptions.

Prescription Hearing Aid Labeling--§ 801.422 (Third-Party Disclosure):

Proposed § 801.422(c) sets forth labeling requirements for prescription hearing aids. However, as with some of the provisions under proposed § 800.30(c), we include no estimate for provisions under proposed § 801.422(c)(1)(i)(A) and (B), (c)(2)(i)(A) through (C), and (c)(2)(ii)(A) through (E) because we consider the labeling to be “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public,” consistent with 5 CFR 1320.3(c)(2).

Proposed § 801.422(c)(1) provides the warnings that must be on the outside package labeling and, if applicable, that the prescription hearing aid is used or rebuilt.

Proposed § 801.422(c)(2) describes requirements for prescription hearing aid labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; and additional information that must be included in the user instructional brochure.

Proposed § 801.422(c)(3) provides the requirements for the labeling on a prescription hearing aid itself, specifically, name of the manufacturer, model name or number, serial number, and year of manufacture; as well as information regarding the battery if applicable; and if the prescription hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Proposed § 800.422(c)(4) provides the technical specification elements that must appear in the user instructional brochure or in separate labeling that accompanies the device.

The PRIA estimates that 105 firms manufacture air conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under proposed §§ 800.30(c)(2) and 801.422(c)(2)).

The proposed rule would necessitate the relabeling of all current hearing aids (approximately 840) according to either the proposed OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the PRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

We request comments on these estimates and assumptions.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through <https://www.reginfo.gov/public/do/PRAMain> (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the *Federal Register*.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires Agencies to “construe...a Federal statute to preempt State law only where the statute contains an express preemption provision or where there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from, or in addition to, any requirement applicable under” chapter V of the FD&C Act that is applicable to devices. (See section 521 of the FD&C Act; *Medtronic v. Lohr*, 518 U.S. 470 (1996); and *Riegel v. Medtronic*, 552 U.S. 312 (2008)). Federal law also preempts State or local laws “specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of [OTC hearing aids] through in-person transactions, by mail, or online, that [are] different from, in addition to, or otherwise not identical to, the regulations promulgated under” section 709(b) of FDARA (see section 709(b)(4) of FDARA).

Section 521(b) of the FD&C Act provides that the Commissioner of Food and Drugs may, upon application of a State or local government, exempt a requirement from preemption, if the State or local requirement for the device is more stringent than the requirement under the FD&C Act, or if the requirement is necessitated by compelling local conditions and compliance with it would not cause the device to be in violation of a requirement under the FD&C Act.” Following this process, and if this rule becomes final, a State or local government may request an

exemption from preemption for those State or local requirements pertaining to hearing aid products that are preempted by the Agency's final rule under section 521 of the FD&C Act. However, because FDARA does not provide a parallel mechanism to exempt State or local requirements from its express preemption provision, FDA is not considering exemptions under section 709(b)(4) of FDARA for OTC hearing aids.

Thus, if this proposed rule is made final, the final rule would create requirements that fall within the scope of section 521 of the FD&C Act and/or section 709(b)(4) of FDARA. If made final, it would also amend § 801.420 and repeal § 801.421, and such changes would affect many of the decisions on applications for exemption from preemption that were issued in relation to these two regulations under section 521(b) of the FD&C Act, resulting in the removal of the regulations codifying such decisions, as discussed further in section III.I. above. The scope of preemption of this proposed rule, if finalized, is discussed in more detail in sections III.G through I, above.

X. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at

<https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only with the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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List of Subjects

21 CFR Part 800

Administrative practice and procedure, Incorporation by reference, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR parts 800, 801, 808, and 874 be amended as follows:

PART 800--GENERAL

1. The authority citation for part 800 is revised to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360j, 360k, 361, 362, 371.

Section 800.30 also issued under Sec. 709, Pub. L. 115-52, 131 Stat. 1065-67.

2. Add § 800.30 to subpart B to read as follows:

§ 800.30 Over-the-Counter Hearing Aid Controls.

(a) *Scope.* This section specifies the requirements for over-the-counter (OTC) air-conduction hearing aids. Air-conduction hearing aids that satisfy the requirements in paragraphs (c) through (f) of this section are considered “available” over the counter as section 520(q)(1)(A)(v) of the Federal Food, Drug, and Cosmetic Act uses the term. Air-conduction hearing aids that do not meet the definition in section 520(q) of the Federal Food, Drug, and Cosmetic Act and do not satisfy the following requirements are prescription hearing aids. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Licensed person. A licensed person is a person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act that holds a license or degree for the diagnosis, assessment, or treatment of hearing loss; or that holds a license to sell or distribute hearing aids. A person that must meet generally applicable licensing or operating requirements such as annual health and safety inspections, provided the generally applicable licensing or operating requirement is consistent with this section and other applicable requirements under the Federal Food, Drug, and

Cosmetic Act, is not a “licensed person” solely for that reason. A person that represents as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) is not a “licensed person” solely by making such representations.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user’s hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Tools, tests, or software. Tools, tests, or software are components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device’s output, to meet the user’s hearing needs.

Used hearing aid. A hearing aid is “used” if a user has worn it for any period of time. However, a hearing aid shall not be “used” merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is “bona fide” if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* An OTC hearing aid shall bear all of the following in the labeling.

(1) *Outside package labeling.* The outside package of an OTC hearing aid shall bear all of the following:

(i) *Warnings and other important information.* All of the following shall appear on the outside package:

(A) *Warning against use in people younger than 18.--*

WARNING: If you are younger than 18, do not use this.

You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) *Symptoms suggesting perceived mild to moderate hearing loss.--*

This hearing aid is designed and intended for perceived mild to moderate hearing loss in adults. If you experience any of the following, you may have this kind of hearing loss:

- Difficulty hearing or understanding conversations, especially in groups or noisy places, or when you can't see who is talking
- Difficulty hearing while using a telephone
- Fatigue due to greater listening effort
- Needing to turn up the volume of television, radio, or music louder than normal or loud enough for others to complain

(C) *Advice of availability of professional services.--*

Important Information: You can seek assistance from a hearing healthcare professional.

This device may not be useful for more significant hearing loss or complicated hearing needs. If you cannot hear conversations in a quiet environment, or you have trouble hearing loud sounds—for example, loud music, motor vehicles, power tools, noisy appliances—this device may not help you hear better. If you try this device and continue to struggle with or remain concerned about your hearing, you should seek a consultation with a hearing healthcare professional.

(D) *“Red flag” conditions.--*

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(E) Notice of weblink and telephone number for information.--

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] to request a paper copy of this information and other labeling.

(F) Notice of manufacturer's return policy.--

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

(ii) Statement of build condition. If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(2) Labeling, inside the package. The manufacturer or distributor of an OTC hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18.--*

WARNING: If you are younger than 18, do not use this. You should go to a doctor because your condition needs specialized evaluation and management. Over-the-counter hearing aids are only for users who are age 18 and older.

This over-the-counter hearing aid is for users age 18 and older to compensate for perceived mild-to-moderate hearing impairment. A younger person with hearing loss should see a licensed physician, preferably an ear specialist, for diagnosis of potential associated medical conditions. Furthermore, children should receive a formal hearing evaluation and rehabilitation since hearing loss may cause problems in language development and educational and social growth of a child.

(B) *“Red flag” conditions.--*

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(C) *Warning about pain from device placement.--*

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when inserting or placing it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. You may also report this to FDA as an adverse event according to the instructions that appear later.

(ii) Any additional warnings the manufacturer may include prior to the caution and notices to users in paragraph (c)(2)(iii) of this section.

(iii) The following caution and notices for users, which shall appear prior to any content except the cover page and the warnings under paragraphs (c)(2)(i) and (ii) of this section:

(A) *Caution about hearing protection.--*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) *Caution about excessive sound output.--*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) *Advice to seek professional services.--*

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

(D) *Note about user expectations.--*

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.--*

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088.

- (iv) An illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment.
- (v) Information on the function of all controls intended for user adjustment.
- (vi) A description of any accessory that accompanies the OTC hearing aid, including but not limited to wax guards and accessories for use with a computer, television, or telephone.
- (vii) Specific instructions for all of the following:
 - (A) Instructions for sizing or inserting the eartip of the OTC hearing aid to prevent insertion past the bony-cartilaginous junction of the external auditory canal and damage to the tympanic membrane.
 - (B) The tools, tests, or software that allow the user to control the OTC hearing aid, including self-select, self-fit, and self-check the performance of the OTC hearing aid, and customize it to the user's hearing needs, including information about properly fitting eartips.
 - (C) Use of the OTC hearing aid with any accompanying accessories.
 - (D) Maintenance and care of the OTC hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.
 - (E) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.
 - (F) Expected battery life.

(G) Any other information necessary for adequate directions for use as defined in § 801.5.

(viii) Identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) The technical specifications required by paragraph (c)(4) of this section.

(x) A description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid, including but not limited to ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(xi) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xii) If the manufacturer provides a repair service or licenses or certifies third-party repair services, information on how and where to obtain repair service, including at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service.

(xiii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the OTC hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on an OTC hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a “+” symbol to indicate the positive terminal for battery insertion unless the battery’s physical design prevents inserting the battery in the reversed position.

(iii) If the OTC hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* All of the following technical specifications shall appear in the user instructional brochure that accompanies the device. You may additionally include it on the outside package.

(i) The maximum output limit value (OSPL90).

(ii) The full-on gain value, which is the gain with a 50 dB SPL pure-tone input and volume set to full on.

(iii) The total harmonic distortion value.

(iv) The self-generated noise value.

(v) The latency value.

(vi) The upper and lower cutoff frequencies for bandwidth.

(d) *Output limits.* The output limit for an OTC hearing aid shall be the device maximum acoustic output sound pressure level (SPL) in a 2-cubic centimeter (cm³) coupler when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. An OTC hearing aid shall not exceed the following limits:

(1) *General output limit.* An OTC hearing aid shall not exceed an output limit of 115 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) *Output limit for a device with input-controlled compression and user-adjustable volume control.* An OTC hearing aid that includes input-controlled compression and a user-adjustable volume control shall not exceed an output limit of 120 dB SPL at any frequency.

(e) *Electroacoustic performance limits.* An OTC hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using a 2-cm³ coupler where applicable.

(1) *Output distortion control limits.* Test the output distortion of the OTC hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method:

(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-Hz one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the OTC hearing aid.

(iii) You must measure the output distortion at the OTC hearing aid's maximum volume and the input sound level to the OTC hearing aid adjusted to produce the required outputs.

(2) *Self-generated noise level limits.* Self-generated noise shall not exceed 32 dB SPL. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) *Latency.* Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) *Frequency response bandwidth.* The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(5) *Frequency response smoothness.* No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA-2051:2017.

(f) *Design requirements.* An OTC hearing aid must conform to all of the following design requirements.

(1) *Insertion depth.* The design of an OTC hearing aid shall limit the insertion of the eartip to the bony-cartilaginous junction of the external auditory canal and no deeper.

(2) *Use of atraumatic materials.* The material for the eartip of an OTC hearing aid shall be atraumatic.

(3) *Proper physical fit.* The OTC hearing aid shall be designed to enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

(4) *Tools, tests, or software.* The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

(g) *Condition for sale of an OTC hearing aid.* The sale of an OTC hearing aid to or for a person younger than 18 years of age is prohibited.

(h) *Effect on State law.* Any State or local government requirement for an OTC hearing aid is preempted to the following extent.

(1) *Preemption.* No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

(2) *Professional requirements.--(A) General rule.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any

product or to all places of business regardless of whether they sell OTC hearing aids. However, although a State or local government may not require the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

(B) *Sale of OTC hearing aids is not an exemption.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids does not exempt a person from any State or local government's professional or establishment requirements that are consistent with this section.

(C) *Representations may create professional obligations.* A person shall not incur specialized obligations by representing as a servicer, marketer, seller, dispenser, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.

(3) *Private remedies.* This section does not modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(i) *Incorporation by reference.* (A) The standard required in this section is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov or go to https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(B) *ANSI*. The American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036, storemanager@ansi.org, <https://www.ansi.org>, 202-293-8020.

(I) ANSI/CTA-2051, “Personal Sound Amplification Performance Criteria,” clause 4.1, dated January 2017.

(2) [Reserved]

(ii) [Reserved]

PART 801--LABELING

3. The authority citation for part 801 is revised to read as follows:

Authority: 21 U.S.C. 321, 331-334, 351, 352, 360d, 360i, 360j, 371, 374.

§ 801.420 [Removed]

4. Remove § 801.420.

§ 801.421 [Removed]

5. Remove § 801.421.

6. Add § 801.422 to subpart H to read as follows:

§ 801.422 Prescription hearing aid labeling.

(a) *Scope*. This section specifies the labeling requirements for prescription hearing aids. Any hearing aid that does not satisfy the requirements of § 800.30 of this chapter shall be a prescription device. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation. This section does not apply to group auditory trainers.

(b) *Definitions for the purposes of this section*. This section uses the following definitions:

Dispenser. A dispenser is any person, as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act, engaged in the sale of prescription hearing aids to any member of the consuming public or any employee, agent, salesperson, and/or representative of such a person.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an over-the-counter (OTC) hearing aid as defined in § 800.30 of this chapter or a hearing aid that does not satisfy the requirements in § 800.30 of this chapter.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Used hearing aid. A hearing aid is “used” if a user has worn it for any period of time. However, a hearing aid shall not be “used” merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is “bona fide” if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* A prescription hearing aid shall bear all of the following labeling.

(1) *Outside package labeling.* The outside package of a prescription hearing aid shall bear all of the following:

(i) *Warnings.* All of the following shall appear on the outside package:

(A) *Warning against use in people younger than 18 without prior medical evaluation.--*

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *“Red flag” conditions.--*

WARNING: Conditions that Require Medical Care

Prior to purchasing this device, you should promptly consult with a licensed physician, preferably an ear specialist, if you have any of the following:

- Visible deformity of the ear, either present since birth or from trauma
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodes of vertigo (a sensation of spinning or swaying) or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears

(ii) *Notices.* All of the following shall appear on the outside package:

(A) *Note about device trial options.--*

Note: Ask about trial-rental or purchase-option programs.

If you are unsure about your ability to adapt to using a hearing aid, you should ask about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers offer programs that allow you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

(B) *Statement of build condition.* If the prescription hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(2) *Labeling, inside the package.* The manufacturer or distributor of a prescription hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18 without prior medical evaluation.--*

WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a licensed physician, preferably an ear specialist. Prior to purchase, a physician should determine that the person is a candidate for the use of a hearing aid.

(B) *“Red flag” conditions, addressed to dispensers.--*

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a licensed physician, preferably an ear specialist, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear in the past 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Episodic vertigo or severe dizziness
- Sudden, quickly worsening, or fluctuating hearing loss in the past 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

(C) *Warning to dispensers about very high-output devices.--*

WARNING to Hearing Aid Dispensers, Outputs in excess of 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

(ii) The following caution and notices for users, which shall appear prior to any content, except the cover page and the warnings under paragraph (c)(2)(i) of this section:

(A) *Caution about hearing protection.--*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, either of short or long duration. You should use appropriate hearing protection in loud environments. As a general rule, if you would use ear plugs in a loud environment, you should remove this device and use ear plugs in that environment.

(B) Caution about excessive sound output.--

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful.

(C) Note about user expectations.--

Note: Expectations about what a hearing aid can do

A hearing aid will not restore normal hearing and may not completely eliminate difficulty hearing over noise. Further, a hearing aid will not prevent or improve a hearing impairment resulting from a medical condition(s).

For many people, the use of a hearing aid may be more satisfactory with training or counseling because the device is only one part of hearing habilitation.

Also, if you have hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid, especially in demanding listening situations—for example, noisy environments.

(D) Note about reporting adverse events to FDA.--

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report an adverse event, you should submit the information to FDA as soon as possible after the event. Adverse events can include: ear canal or outer ear skin irritation, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device lodged in your ear canal, sudden increased severity in hearing loss with device use, etc.

Instructions for reporting are available at <https://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088.

(E) Note about hearing loss in people younger than 18 and fitting devices.--

Note: Hearing loss in people younger than 18

- If you're younger than 18, you should see a doctor first, preferably an ear specialist.
- The doctor will identify and treat medical conditions when appropriate.
- The doctor may refer you to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the right hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a licensed physician, preferably an ear specialist, before the purchase of a hearing aid. Licensed physicians who specialize in the ear are often called otolaryngologists, otologists, or otorhinolaryngologists. The purpose of a medical evaluation is to identify and treat all medical conditions that may affect hearing before the hearing aid is purchased for the person.

Following the medical evaluation and if appropriate, the physician will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The physician may refer you to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the hearing aid candidate's ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist to select and fit a hearing aid to the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

(iii) An illustration(s) of the prescription hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(iv) Information on the function of all controls intended for user adjustment.

(v) A description of any accessory that accompanies the prescription hearing aid, including but not limited to wax guards, and accessories for use with a computer, television, or telephone.

(vi) Specific instructions for all of the following:

(A) Use of the prescription hearing aid with any accompanying accessories.

(B) Maintenance and care of the prescription hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(C) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(D) Expected battery life.

(vii) Identification of any known physiological side effects associated with the use of the prescription hearing aid that may warrant consultation with a physician, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) The technical specifications required by paragraph (c)(4) of this section unless such specifications appear in separate labeling accompanying the prescription hearing aid.

(ix) A description of commonly occurring, avoidable events that could adversely affect or damage the prescription hearing aid, including but not limited to ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(x) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xi) If the manufacturer provides a repair service or licenses or certifies third-party repair services, information on how and where to obtain repair service, including at least one specific address where the user can go or send the prescription hearing aid to obtain such repair service.

(xii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the prescription hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on a prescription hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a “ + ” symbol to indicate the positive terminal for battery insertion unless the battery’s physical design prevents inserting the battery in the reversed position.

(iii) If the prescription hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* Technical specifications useful in selecting, fitting, and checking the performance of the prescription hearing aid shall appear in the user instructional brochure or in separate labeling that accompanies the device. You must determine the technical specification values for the prescription hearing aid labeling in accordance with the test procedures of the American National Standard, “Specification of Hearing Aid Characteristics,” ANSI/ASA S3.22-2014. As a minimum, the user instructional brochure or such other labeling shall include the appropriate values or information for the following technical specification elements as these elements are defined or used in such standard:

- (i) Saturation output curve (SSPL 90 curve).
- (ii) Frequency response curve.
- (iii) Average saturation output (HF-Average SSPL 90).
- (iv) Average full-on gain (HF-Average full-on gain).
- (v) Reference test gain.
- (vi) Frequency range.
- (vii) Total harmonic distortion.
- (viii) Equivalent input noise.
- (ix) Battery current drain.
- (x) Induction coil sensitivity (telephone coil aids only).
- (xi) Input-output curve (only for hearing aids with automatic gain control).
- (xii) Attack and release times (only for hearing aids with automatic gain control).

(5) *Misbranding*. A prescription hearing aid that is not labeled as required under this section and § 801.109 of this chapter shall be misbranded under sections 201(n), 502(a), and/or 502(f) of the Federal Food, Drug, and Cosmetic Act.

(d) *Incorporation by reference*. (1) The standard required in this section is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the Food and Drug Administration, Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov or go to https://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(2) *ANSI*. The American National Standards Institute, 1889 L Street NW, 11th floor, Washington, DC 20036, storemanager@ansi.org, <https://www.ansi.org>, 202-293-8020.

(i) ANSI/ASA S3.22-2014, “Specification of Hearing Aid Characteristics,” dated November 2014.

(ii) [Reserved]

PART 808--EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

7. The authority citation for part 808 is revised to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371.

Section 808.1 also issued under Sec. 709, Pub. L. 115-52, 131 Stat. 1065-67.

PART 808 [AMENDED]

8. In part 808, remove the words “the act” and add in their place “the Federal Food, Drug, and Cosmetic Act”.

9. In § 808.1, add headings to paragraphs (a) through (f) and add paragraph (g) to read as follows:

§ 808.1 Scope.

(a) *Introduction.* * * *

(b) *General rule for State and local requirements respecting devices.* * * *

(c) *Exempting from preemption certain State or local requirements respecting devices.*

* * *

(d) *Meaning of “requirements applicable to a device.”* * * *

(e) *Determination of equivalence or difference of requirements applicable to a device.*

* * *

(f) *Applicability of Federal requirements respecting devices.* * * *

(g) *Exemptions not applicable to certain State or local government requirements specifically related to hearing products.* An exemption under this part shall not apply to any State or local government law, regulation, order, or other requirement specifically related to hearing products, including any requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids, that:

(1) Would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online; and

(2) Is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017.

10. Revise §808.3 to read as follows:

§ 808.3 Definitions.

Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.

Political subdivision or locality means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

State means any State or Territory of the United States, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.53 [Removed and Reserved]

11. Remove and reserve § 808.53.

12. Revise § 808.55 to read as follows:

§ 808.55 California.

The following California medical device requirements are preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act, and FDA has denied them exemption from preemption:

(a) *Medical devices; general provisions.* Sherman Food, Drug, and Cosmetic Law, Division 21 of the California Health and Safety Code, sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26441, to the extent that they apply to devices; and

(b) *Ophthalmic devices; quality standards.* California Business and Professions Code, section 2541.3 to the extent that it requires adoption of the American National Standards Institute standards Z-80.1 and Z-80.2.

§§ 808.57 through 808.101 [Removed and Reserved]

13. Remove and reserve §§ 808.57 through 808.101.

PART 874--EAR, NOSE, AND THROAT DEVICES

14. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

15. Redesignate § 874.3300 as § 874.3301 and revise to read as follows:

§ 874.3301 Bone-conduction hearing aid.

(a) *Identification.* A bone-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that transmits sound to the inner ear through the skull. A bone-conduction hearing aid is subject to the requirements in § 801.422 of this chapter.

(b) *Classification.* Class II.

16. Revise § 874.3305 to read as follows:

§ 874.3305 Air-conduction hearing aid.

(a) *Identification.* An air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing that conducts sound to the ear through the air. An air-conduction hearing aid may be wireless, self-fitting, or both. An air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable. Air-conduction hearing aid generic types exclude the group hearing aid or group auditory trainer, master hearing aid, and the tinnitus masker, regulated under §§ 874.3320, 874.3330, and 874.3400, respectively.

(b) *Classification.* (1) *Legacy hearing aid.* Class I for an air-conduction hearing aid that is not a wireless or self-fitting device. This hearing aid is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

(2) *Wireless hearing aid.* Class II (special controls) for an air-conduction hearing aid that incorporates wireless technology in its programming or use. A wireless hearing aid may also be a self-fitting hearing aid. A wireless hearing aid that is not a self-fitting hearing aid is exempt from

the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. The special controls for a wireless hearing aid are:

(i) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device;

(ii) Performance testing must validate safety of exposure to non-ionizing radiation; and

(iii) Performance data must validate wireless technology functions.

(3) *Self-fitting hearing aid*. Class II (special controls) for a wireless air-conduction hearing aid that incorporates technology, including software, that allows users to program their hearing aids. This technology integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fittings and settings. A self-fitting hearing aid is not exempt from premarket notification procedures, notwithstanding the exemption in paragraph (b)(2) of this section. The special controls for a self-fitting hearing aid, in addition to the special controls for a wireless hearing aid if the device incorporates wireless technology, are:

(i) Clinical data must evaluate the effectiveness of the self-fitting strategy;

(ii) Electroacoustic parameters, including maximum output limits, distortion levels, self-generated noise levels, latency, and frequency response, must be specified and tested;

(iii) Software verification, validation, and hazard analysis must be performed; and

(iv) Usability testing must demonstrate that users can correctly use the device as intended under anticipated conditions of use.

17. In § 874.3315, revise paragraph (a) to read as follows:

§ 874.3315 Tympanic membrane contact hearing aid.

(a) *Identification*. A tympanic membrane contact hearing aid is a prescription wearable device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane.

A tympanic membrane contact hearing aid is subject to the requirements in § 801.422 of this chapter.

* * * * *

§ 874.3325 [Removed]

18. Remove § 874.3325.

19. In § 874.3950, add a sentence at the end of paragraph (a) to read as follows:

§ 874.3950 Transcutaneous air conduction hearing aid system.

(a) * * * A transcutaneous air conduction hearing aid system is subject to the requirements in § 801.422 of this chapter.

* * * * *

Dated: October 8, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

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